ISOC 1

Indian Standards of Care

Indian Standards of Care for Persons with Gender Incongruence and People with differences in Sexual Development/Orientation

INDIAN PROFESSIONAL ASSOCIATION FOR TRANSGENDER HEALTH

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Association for Transgender Health in India

ISBN 978-81-942183-5-7

Preface

Why Indian Standards of Care?

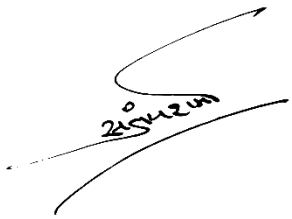
Gender for "humans" is more a matter of the "Being" rather than the "Body". It is perception of "Who am I?" arising as a result of neural connections made in the biochemical milieu during early development, shaped by environmental influences. It is the pedestal on which the construct of "I" stands. It is an outcome of who one identifies as, the "my kind", prompted by the "cues" others around them provide, the "who, the person is expected to be", based on their own perception of "who, the person in question is". A mismatch of the perception of others with that of the individual is what is termed as Gender Incongruence. The degree of incongruence is propagated by the perception and behavior of the majority in the environment, magnified by their degree of acceptance of diversity which is deeply rooted in the culture and societal norms of the place that the individual belongs to. It has been unequivocally endorsed by the strength of scientific evidence that favorable outcome is directly proportional to the resilience shown by the immediate family and willingness of the care-providers to help the individual navigate the societal hurdles. The task is compounded by the binary viewpoint and poor understanding of the "Transgender Experience" by the agencies, entrusted with the task of giving succor. To make matters worse the majority of the transgender persons have poor health-seeking behaviour as a result of the judgmental attitude of the care providers. The misinformed impressionable "client" is drawn to "Procedures" being offered in an unethical covert manner to a privileged few who can afford the high costs. The nonexistence of Indian Standards of Care and nonadherence to existing protocols in the above situation caused more harm than good, hence necessitating the development of Standards of Care which are both current and Indian in content and context for addressing the needs of the persons with Gender Incongruence and people with differences in sexual development /orientation.

The seed for "ISOC-1: Indian Standards of Care for persons with Gender Incongruence and people with differences in sexual development /orientation" was planted by the "Association for Transgender Health in India (ATHI)" in its first International Conference on Transgender Healthcare, IPATHCON 2019, organized in collaboration with Jamia Hamdard deemed to be university, at New Delhi, on the 1st and 2nd November 2019, wherein more than 200 professionals from various specialties and subspecialities, both from the medical and social sciences, working in the field of Transgender Healthcare came together on a single platform to share their academic and clinical experiences and interacted with members of the community in order to understand and address their felt needs. Enriched by the collective experience and encouraged by the success of IPATHCON 2019, a core group of professionals, allies and community members, cutting across various specialties, took on the onerous task of revisiting the rich heritage of the Indian culture which has celebrated and worshipped diversity, reviewing the existing guidelines and current medical evidence, brainstorming with policy makers to curate the best. It is indeed a result of their hard work that we announce with a resounding "Yes" on the 1st of November 2020, the release of benchmark document ISOC-1 to the medical fraternity during the IPATHCON 2020 aptly themed "Indian Standards of Care, are we there?"

The ISOC-1 endorses the progressive view of WHO which has de-pathologized Gender Incongruence and seeks to fill the lacunae in Transgender Healthcare by formulating best practices which are in sync with the globally accepted Standards of Care published by WPATH, SOC 7 and based on the emerging evidence that conflict arising as a result of incongruity between assigned sex and desired gender magnifies dysphoria and non-resolution may further distort psychosocial development compounded by the insensitive callous attitude of the cisgender majority, perpetuating an environment of mistrust and intolerance forcing the gender incongruent person to further harm at the hands of unscrupulous professionals who peddle pseudo-scientific 'quick fix' procedures.

ISOC-1 is a proponent of Affirmative Care, favoring early recognition of gender incongruity, provisioning of a gender-sensitive environment for psychosocial development and early access to Healthcare services stressing the need for adopting a multipronged proactive approach for the management of gender incongruence. The ISOC-1 aspires to be the base document for addressing the stakeholders' felt-need to acquire and share knowledge, facilitate the delivery of multispecialty Healthcare, empower through advocacy and implement legislation. It presses for a holistic public health approach to be adopted by all agencies, both Governmental and Non-Governmental, working to ensure equity in the delivery of Healthcare and mandates that existing policies be reworked to address the cause rather than manage the outcomes.

ISOC-1 seeks to be a dynamic document, constantly evolving and stimulating the professionals working in the field of Transgender Health, educationists, academicians, social workers, and community members to step out of their silos, interact with each other, undertake research and share their experiences to improve the successive editions of the Indian Standards of Care, making it a benchmark document for providing holistic and affordable Healthcare to all human forms irrespective of their self-affirmed gender identity or sexual orientation, harnessing the time tested strengths and expertise of the various national and international agencies working with or assisting the government to provide Social Justice and Health for All, laying the foundation of an all-inclusive society, wherein, all forms of gender identity and expression are nurtured and celebrated, where, new abilities emerging as a result of scientific progress permit all form of the human to live in harmony with dignity, embracing diversity and enjoying equal rights and privileges, as bestowed by the constitution.



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Gender Affirmative Surgical Care

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Surgical Management of Gender Incongruence

Physical 'sex' of a person is determined by the phenotype and is assigned at birth usually by parents and the physician. On the other hand, the word 'Gender' refers to our psychological identification of self and its expression. Normally, our physical sex and 'gender' are in alignment. In a few individuals, there is a noticeable and persistent incongruence between 'sex' and 'gender' to an extent, that the individual wishes to get rid of one's primary and/or secondary sexual characteristics and acquire the characteristics of a gender, which is different from that of assigned (birth) sex/ gender (DSM5)[1]. The need to express one's desired gender and for the society to accept them in this role, and their treatment by the society gives rise to a deep seated pain referred to as 'Gender Incongruence' (ICD11)[2], (previously dysphoria (DSM5)). Genital and non- genital gender affirmative surgery helps in alleviation of gender incongruence and the associated conditions such as anxiety and depression. It is important to work as part of a gender team for the purpose of shared decision making and comprehensive management under one roof. Generally, in India, individuals seek information about professionals through social media and from persons, who have undergone gender affirmative care. Around 50% of the individuals at presentation are unsure, regarding how to proceed further, Remaining individuals wish to know about specific procedures and the results. Almost all individuals wish to know the costs involved at the outset. Around 25 years ago, individuals used to present in clinics with their partners/ friends/ cousins and were in late twenties and thirties. These days most individuals present in their teens or early twenties and are accompanied by their parents. This represents a significant shift in Indian people's attitude to gender incongruent persons, and a more trans friendly environment. As per law, any irreversible intervention such as surgery can be only be carried out after the age of legal majority, which is 18 years in India.

Ideally, the Gender Identity Clinic should be in a discrete area of the hospital and have dedicated entry and exit. The registration area for these should be separate from general patients and there should be a provision in hospital information system (HIS) to include individual's desired name and gender in all documents. The hospital documents may include the above as well as name and gender as per legal identity proofs, for medicolegal purposes. The washrooms should be gender neutral and clinic staff should be gender sensitized. One should ask the individual regarding the preferred pronoun, as well as which sexed chaperone should be present with the examining surgeon. After the interview, individual should be given a definite algorithm to follow for achieving a smooth transition. Our current algorithm is broadly based on 7th version of Standards of Care for the health of transsexual, transgender and gender nonconforming people (7th SOC's[3]) published by the World Professional Association for Transgender Health (WPATH), modified by our (the Indian) experience. 7th SOC's recommend one referral from a board- certified mental health professionals working in this field prior to any breast surgery and two such referrals prior to genital surgery. The letters of recommendation should include the individual's demographic data, results of psychological assessment including diagnosis, the duration of evaluation and therapy, a statement that any underlying mental health issues have been addressed, the individual is well informed about the irreversible nature of surgery and informed consent has been taken, that the criteria for recommending surgery have been met and that the mental health professional is available for any coordination of care. It's also important to contact the individual's mental health professional for validation of referral prior to performing surgery.

Generally, for breast surgery (reduction in case of transmen and augmentation in case of transwomen), letter from only mental health professional is required. Also, only one letter is required for initiation of hormone therapy. However, we prefer to obtain both recommendations at the outset, as we feel that it makes the path to individual's transition smoother and there is a higher certainty in diagnosis. We also prefer to take these letters of recommendation from two different mental health teams, though it is not mandatory. If one such teams is from our hospital, then we prefer the other referral letter from a team outside the hospital to remove any iota of bias. As most of the individuals are from out of state, it suits them to take such letters from a mental health professional in their state, as it avoids unnecessary expenditure of time and money. We have a pool of mental health professionals in the Association for Transgender Health in India (ATHI) and Indian Professional Association for Transgender Health (IPATH) family with interest in this field, who provide the necessary mental health analysis, diagnosis, therapy, referrals and are available for professional interaction.

Hormonal Intervention plays an important role in the management of gender incongruence. It eases the individual's transition into the desired gender role. Deepening of voice, growth of beard and moustache hair, shifts in body fat distribution to masculine and better definition and development of musculature goes a long way in adapting a transman, who was otherwise a biologic woman, in the desired male gender role. Likewise, development of breasts, shifts in body fat resulting in feminine curves, smoother skin, reversal of male pattern baldness with better scalp hair growth help the transition of a transwoman, who was otherwise a biologic man, in a female gender role. Post orchidectomy in transwomen, the hormone therapy also plays an important role in bone health. In effect, hormone therapy provides a real- life experience for gender incongruent persons, as a partially reversible intervention, prior to surgery. Hence, 7th SOC's recommend hormone therapy for 12 months prior to genital surgery for both transmen and transwomen, unless the individual is unwilling to take it, or it is medically contraindicated. It is also recommended for 12 months as an optional criterion, prior to breast augmentation in transwomen, as after 12 months, there is little if any further increase in breast size, and the individual can realistically assess the need for further surgical breast augmentation. However, we feel that we should inform the individual regarding the pros and cons of hormone therapy in their particular case and keep it as an optional intervention only, because many individuals are reluctant to take hormones for fear of side effects in-spite of 6 monthly endocrine follow-up. It is also important to stop oral estradiol therapy 2-4 weeks prior to any surgery, to obviate the increased risk of venous thromboembolism.

Although the procedure of informed consents is well established, and there is a legal precedence in the form of Bidhan Baruah Judgment[4], when a division bench of Mumbai High Court observed that- there is no law which prohibits sex change operation and an adult (>18years) can undergo sex change operation without the need of parental consent, the gender affirmative surgeries still involve removal of normal organs. There have been instances in the past, when the surgeons were sued by the individuals, pleading that the, individual had not understood the consent or, the surgery was forced upon them. Hence in India, we prefer to involve the court in the form of a notarized affidavit on a Rs 100/- stamp paper, called 'Waiver of Liability Affidavit'[5], in which the individual promises not to sue the treating team for undertaking the individual's surgeries. The affidavit explains the individual's circumstances and releases the operating team for removing the individual's normal sexual

organs, causing irreversible loss of current sexual functioning and fertility. In case the individual is married, a spousal release affidavit may also need to be notarized for extra caution, though it is not legally necessary. Although these affidavits cause some extra expense to the individual, and the added discomfort of having to visit courts, these also go a long way in smoothening the relationship with the doctor. These affidavits also imply that the state has been informed and the individual has had adequate opportunity and time to think about the implications of gender affirmative surgeries.

In India, a large set of third gender/ transgender persons consist of biologic males with feminine gender expression, who have been castrated either before or after development of secondary sexual characteristics. These individuals have often undergone penectomy, orchidectomy and scrotectomy at the hands of unqualified persons in a ceremony called 'Nirvan'. They often present in GICs with absent external genitalia or a shallow vaginal pit, with desire for corrective surgeries such as vaginoplasty or breast augmentation. The standard requirements for trans persons do not apply in such cases, as there are no normal tissues to be removed and any surgery undertaken is likely to be a corrective surgery. Hence, consults and referrals or recommendation letters from mental health professionals and waiver of liability affidavits are not required in such situations.

It is important for the surgeon to educate the individuals and devise a customized algorithm in their quest for surgical transition to the desired gender role. Living in a gender congruent role for at least 12 months, as mentioned in 7th SOC's is very important for the individual, before undergoing genital surgery such as Phalloplasty/ Metaidoioplasty or Vaginoplasty. This provides a real- life experience of living in desired gender role in all seasons, gaining a first-hand experience, and resolving any conflicts regarding gender expression and sexuality prior to undergoing the irreversible genital transformation, thus decreasing the chances of regret. Surgeons should also inform the individuals about success rates and complications of various procedures, so that they get adequate time and opportunity to make informed choices regarding their transition. For example, phalloplasty is a complex and long procedure with a significant incidence of urinary complications such as stricture (narrowing of urinary stream or blockage) or fistula (leakage of urine). While metaidoioplasty, which consists of enlargement of clitoris and advancement of urethra (urine pipe) to clitoral tip is a relatively simple procedure with less urinary complications, enables orgasm but does not enable the individual to engage in penetrative sexual intercourse, or to void urine in a standing position in all cases. An informed individual can thus select either procedure depending on expense, number of stages, time duration, complications and need for corrective surgeries. Another example is the type of phalloplasty. Two of the commonest methods of neo-penis reconstruction are free Radial forearm free flap phalloplasty (fRAFFp) and pedicled Anterolateral thigh flap phalloplasty (pALTp). Most of the transmen at first presentation in our experience have already decided on getting operated by one of these methods. Phalloplasty is usually the last major core procedure in transition to the male gender role. Hence, those individuals who opt for fRAFFp are advised to preserve the veins in non-dominant forearm, and not allow blood sampling or venous cannulation during preceding procedures such as top surgery and the surgery for removal of uterus, tubes, ovary and vagina (HSOV). This helps to keep the superficial venous system in that forearm uninjured, and hence facilitates the final procedure. In those opting for pALTp, we often harvest vaginal mucosa during HSOV and prelaminate the designated donor thigh with mucosa during this procedure.

When phalloplasty is carried out few months later, the phallus already has a mucosa lined mature urethral tube.

Generally, core procedures are those, which are carried out in all gender incongruent persons, while ancillary procedures are the ones, that are carried out on demand. Ancillary procedures do not require any letters of recommendation from mental health professionals, and some may be carried out before the core procedures. The procedures are detailed in table 1[6]

Table-1

Core surgical procedures for transwomen	**orchidectomy** **penectomy** **vaginoplasty** **clitoroplasty** **labiaplasty and vulvoplasty.** **breast augmentation.**
Core surgical procedures for transmen	reduction mammoplasty (the top surgery) hysterectomy and bilateral salpingo-oophorectomy vaginectomy phalloplasty or metaidoioplasty scrotoplasty urethroplasty placement of testicular prosthesis and placement of an erectile implant/ penile prosthesis

Ancillary procedures for both transmen and transwomen	Hair transplants advancement of hairline/ forehead reduction Pectoral/ Calf implants facial feminizing/ masculinizing/ harmonizing surgery rhinoplasty thyroid chondroplasty and voice affirmative surgery Thoracic shaping Abdominoplasty, liposuction, high definition body contouring. Non-invasive aesthetic procedures.

Surgical Procedures in gender incongruent people:

1) **Core surgeries in transwomen:**
   i) **Breast augmentation**: Breast development occurs once the individual initiates feminizing hormone therapy. However, after a 12- month period on feminizing hormones, there is little if any increase. Also, this enlargement is hemispherical and conical, and without distinctive feminine curves or natural ptosis. Therefore, many transwomen opt for surgical breast augmentation, often without waiting for this 12- months period. There are two common methods for breast augmentation-
      a) **Autologous fat grafting**- In this procedure, fat is harvested from an area in which there is excess- such as abdomen, love handles, thighs etc. under low suction pressure. This fat is then filtered, centrifuged, gravity sedimented and decanted or otherwise processed in Operation Theatre itself to obtain the infiltrate, which has been shown to consists of purified fat cells, stromal vascular fraction, and adipose derived stem cells. This infiltrate is then injected into the appropriate area on chest wall for breast development. 1-4 sittings may be required, at intervals of 4-6 weeks each for optimum breast development to take place.
      b) **Breast augmentation with implant**- Cohesive silicone gel implants are used for augmentation, commonly via inframammary or axillary approach. In contrast to transwomen, biologic women have extra

mammary fat overlying the origins and insertions on muscles in chest wall and axilla, thus softening the contours. Also, their thorax is shorter and more conical. As a result, to compensate for this, transwomen generally opt for larger size implants.

ii) **Vaginoplasty, clitoroplasty, labiaplasty, vulvoplasty, corporectomy and feminizing urethroplasty:** The goals of the procedure are to create a perineo-genital complex, which is aesthetic and as feminine as possible, free of scars and painful neuromas, a vagina of adequate depth and dimensions, and lined by self- lubricating, elastic and hairless epithelium, sensate and with correct axis. The urinary stream should be downwards in a sitting position. Unlike neovaginoplasty (NVP) in biologic women, this procedure is more difficult in transwomen, on account of differences as enumerated in Table 2. Initial steps, which are common to all procedures are- careful dissection of the neovaginal cavity between urinary bladder and rectum, avoiding injury to these important organs. This cavity then needs to be lined by a skin flap or skin graft to prevent its collapse. Otherwise the body will treat it like any other injury or wound and close it in a few days. Currently, the commonest methods for lining the NV cavity are **a) use of penile and/or perineoscrotal skin flaps for lining b) the use of an intestinal segment such as sigmoid colon for vaginal lining c) Laparoscopic peritoneal vaginoplasty.** Authors advise self- dilatation of NV cavity by the individual, for 3 months or till the time of initiating regular vaginal intercourse.

iii) **Ancillary procedures:** These are carried out as per the need, and many transwomen do not require these procedures. If the person suffers from male pattern baldness or receding hairline, this can be readily corrected to approximate a feminine hairline by hairline advancement procedures or hair transplants. Thyroid chondroplasty can be done to reduce Adam's apple. Voice can be feminized by a procedure on larynx, like the tightening of guitar/ violin strings, in a few minutes, under local anaesthesia. A male forehead, which is more prominent with bulging supraorbital ridges, a wide chin, excessively prominent wide cheek bones, square jaws and nasal hump or convex nose, all of these can be feminized by facial feminization surgery and rhinoplasty. Removal of lower floating ribs can be done to mimic the shorter and conical feminine thorax and a narrow waist. Body contouring procedures such as liposuction and abdominoplasty can also be used as per requirement.

Table2- Differences between neovaginoplasty in transwomen and biologic women

NVP comparison	NVP in biologic females	NVP in transsexuals	Implications
Differences in pelvic soft tissues	Pelvis is roomier, with greater space in rectovesical area	There is no rectovesical space. There is just a septum.	Easier dissection. Greater success for techniques such as Vecchietti, Lap Vechietti and Lap assisted balloon NVPs in biologic females.
Differences in bony pelvis (Fang, 2003)*	IIRD 5.2+/- 0.36cms. As bony pelvis is wider, relatively thicker flaps may be used, especially in NVPs for malignant resections.	IIRD 3.95+/- 0.25cms. Chances of bony compression of neovagina, even if a long cavity is created, preventing sexual intercourse.	Only thinnest flaps can be used for transsexual NVPs, such as penile, scrotal skin and grafts.
Differences in pudendal organs	Pudendal organs such as clitoris, labia majora and minora are present. These were sometimes used for reconstructing neovagina.	Pudendal organs also require reconstruction	In transwomen, nearly entire penile tissue except corpora cavernosa is used for reconstruction of pudendal organs. This tissue is often missing in those with castration.

*Fang[7]

2) **Core surgeries in transmen:**

i) **Breast reduction ('the top surgery')-** This is usually the first surgery carried out in transmen. Reduction of the breast mounds enables them to easily pass off as men, while wearing shirts or T shirts, and thus helps alleviate GD. It also frees them from the difficult and painful practice of breast binding and wearing loose fitting shirts. The common methods for breast reduction surgery are **a) inferior periareolar**, if the breasts are relatively small in size**, b) concentric circular**, if these are moderately large, **and c) Excision and free nipple grafting (FNACG),** if the breasts are really large and ptotic.

ii) **Hysterectomy, bilateral salpingo-oophorectomy and vaginectomy (HSOV)-** This procedure differs from the normal gynecological procedure of hysterectomy in the fact, that in biologic women, the vagina is not removed. Additionally, in the HSOV procedure, the authors reconstruct proximal and distal pars fixa urethra, lengthening the female urethra by 5-8cms so that the neo urinary meatus lies anteriorly, almost near pubic bone. This facilitates the urethral anastomosis in subsequent surgeries. Sometimes, the authors also graft the vaginal mucosal lining to form urine pipe or urethra in the future flap, which will be used to form penis at a later stage and date, a process called prelamination. This is especially required in pALTp and sometimes in fRAFFp if the forearm circumference at lower border of flap is less than 15cms or the ulnar aspect of forearm is hairy. Additionally, authors also mobilize bilateral labia majora at this sitting, to form neo-scrotum. This not only provides an additional waterproofing tissue covering over the newly formed urethra, but also enables them to close the perineum completely, as even a small residual pit at the location of obliterated vaginal opening propagates the feeling of gender dysphoria in these individuals.

iii) **Phalloplasty/metaidoioplasty, urethroplasty, scrotoplasty, -** The goal of masculinizing genitoplasty is – to construct or reconstruct genital organs, which aesthetically match the biologic male genitalia, allow the transman to easily micturate in erect position in a male washroom without soiling himself, and to enable him to function as a male partner in penetrative sexual intercourse. In this operative procedure, usually, the most complex of the core surgeries, penis is reconstructed most commonly from **a) the tissues of forearm (free Radial artery forearm flap or fRAFFp), b) thigh (pedicled Anterolateral thigh flap or pALTp) or c) back (free Musculocutaneous latissimus dorsi flap or fMLDp).** Other flaps and sites are used uncommonly. The thigh flap can be transferred directly, but other two procedures require microsurgical free tissue transfer. fRAFFp is still the commonest procedure for phalloplasty, and provides excellent aesthetic result with good sensation, as two nerves are anatomosed, one for general touch and the other for erogenous sensation. However, many transmen do not opt for this procedure, as the skin grafted forearm donor site may be readily visible in short sleeved clothing and could be a giveaway for those conversant with the procedure. The authors carry out glansplasty at the same sitting in fRAFFp. The resultant neo-penis looks like a circumcised erect penis. Urethra is also reconstructed at the same time, by using a part of flap skin rolled inside the outer part (tube in tube method) or using previous prelamination. This penile urethra is anastomosed to the previously advanced urinary meatus to restore the urethral continuity. Previously reconstructed scrotum is now sutured to the ventral proximal edge of neo-penis, thus also providing a waterproofing layer over urethral anastomosis. After the implantation of erectile device 6 months later, the individual can engage in penetrative sexual intercourse, has good erogenous sensation and is able to micturate in erect position without soiling himself. The complication rate of urethral fistula and stricture is close to 40% after phalloplasty. As a result, few

individuals do not opt for phalloplasty, and instead opt for enlargement of clitoris (Metaidoioplasty). In this procedure, the natural clitoral chordee is released and urethra is advanced to the tip of clitoris. Though this procedure does not enable the individual to engage in penetrative sexual intercourse in most cases, it allows for excellent erogenous sensation and orgasm, and in some cases, allows the individuals to micturate in erect position.

iv) **Ancillary procedures:** As there is no other erectile tissue in the body like penile corpora, a reconstructed penis is made in erect size. However, it still lacks the necessary rigidity, to allow vaginal penetration necessary for a sexual intercourse. For this purpose, erectile devices may be implanted in neo-penis, (similar to the devices used in biologic male impotence), usually 6 months after penile reconstruction, when necessary protective sensation has returned. The device can be a malleable rod with hinge, or inflatable prosthesis. Mandibular implants, genioplasty, rhinoplasty etc. can help masculinize a face. Laryngeal surgery can masculinize the voice. Pectoral implants in addition to top surgery can help masculinize the chest. Hi definition body contouring procedures and 'six pack plasty' can help produce an aesthetic masculine abdominal appearance.

Conclusion:

Gender incongruence and variance is a universal and culturally diverse phenomenon. Those persons requiring affirmative procedures should be managed by multidisciplinary teams (GIC's) comprising of various specialists, who are well versed in providing gender sensitive healthcare. Surgical management is a part of the comprehensive management of such persons and helps in alleviating gender incongruence. Not all individuals require every surgical procedure. The surgical care of these individuals needs to be customized to the individual's requirements and a customized algorithm needs to be devised for the purpose early in the treatment. The goal of Gender Affirmation Surgery is to allow these individuals to freely express their gender and perfectly blend in their desired gender role.

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SURGICAL CONSENT FORMS

1) CONSENT FOR BREAST AUGMENTATION SURGERY WITH AUTOLOGOUS FAT IN MALE TO FEMALE GENDER INCONGRUENT INDIVIDUALS

GENERAL INFORMATION

While many gender-incongruent individuals find comfort with their gender identity, role, and expression without surgery, for many others surgery is essential and medically necessary to alleviate their gender incongruence. For the latter group, relief from gender incongruence cannot be achieved without modification of their primary and/or secondary sex characteristics to establish greater congruence with their gender identity and expression.
Usually feminizing hormonal therapy will stimulate breast growth, but a subset of individuals may not be satisfied with this growth alone and may opt for surgical breast augmentation procedure.
As this operation is completely cosmetic elective, a detailed consultation is essential so that you are educated about the procedure. For some trans women (male to female transitioning individuals), feminizing surgery is a natural step, and important to their sense of self. However, many choose not to have surgery. Transgender individuals relate to their bodies differently and need to make individual choices that best fit their requirements.

This is an informed-consent document that has been prepared to educate and inform you regarding augmentation mammaplasty surgery with autologous (own) body fat injections, its risks, as well as alternative treatment(s).
It is important that you read this information carefully and completely.

Preconditions and requirements prior to transfeminine augmentation mammoplasty

1. Persistent, well-documented gender incongruence.
2. Referral letter for surgery from one mental health professional
3. Capacity to make a fully informed decision and to give consent for treatment.
4. Age of majority (18years or more in India)
5. If significant medical or mental health concerns are present, these must be reasonably well controlled.
6. Recommended (not obligate) criterion- 12 months of feminizing hormone therapy prior to this procedure. This results in realistically the maximum breast growth that can occur by non- surgical means, allowing you to take a better decision whether or not to opt for further surgical breast augmentation.

Information regarding autologous fat breast augmentation procedure

Prior to this procedure, external tissue expansion systems like Brava may be prescribed by your surgeon. These devices need to be worn for 10-12 hours daily, for around 4 weeks prior to surgery. Such devices cause temporary expansion of tissues in the area of application (breast), so that more fat graft can be accommodated by breast, and the recipient bed is better prepared to ensure fat graft survival. During the procedure, one's own body fat tissue

is harvested with the help of thin cannulae and low-pressure liposuction procedure. The donor site of fat graft is any area with excessive superficial fat, especially lower abdomen, thighs, flanks, and hip area. The harvested fat is then washed with saline and refined by one of the various methods in operation theatre, such as filtration, centrifugation, gravity sedimentation and decantation, fat refining systems etc leading to removal of contaminants such as saline, oil, cell debris, non- fat tissue etc. The refined fat is then injected into the breast area in subcutaneous, and subglandular/ prepectoral locations to build up the breast volume. Over a period, part of injected fat takes up as a graft and part of it gets absorbed, gets necrosed, forms cyst or gets calcified. At one sitting, only a limited amount of fat can be injected. The fat injection sittings may be repeated at intervals of 4-6 weeks. A total of 1-4 sittings may be required to augment the breast size. Your surgeon will make a few small incisions to insert the cannulae for harvesting fat. There will also be a few small incisions on and around the breast for entry of needles and thin cannulae for injecting fat.

Despite multiple sittings, only moderate breast augmentation (one cup size) is usually achievable by autologous fat injection technique. You should also not be excessively slim, otherwise there will not be sufficient available fat donor area. It may take upto 6 months for final result to appear. Alternatives to this procedure may be silicone gel or saline filled silicone breast implant augmentation. Breast augmentation can also be done with the help of flap transfer of tissues like subcutaneous tissue and muscle into the breast area. You may also, opt, not to undergo breast augmentation.

Risks associated with autologous fat breast augmentation surgery

Note: The listed risks and complications are not all inclusive.

Every surgical procedure has some degree of unavoidable risk. Problems associated with autologous fat breast augmentation procedure, the injected tumescent solution or anaesthesia. It is important that you understand these risks and the possible complications associated with them.

The most common risks associated with injectable fat breast augmentation surgery are as follows:

Bleeding: Very little blood is lost at the time of surgery. It is possible, though unusual, to experience a bleeding episode during or after surgery. Should post-operative bleeding occur, it may require emergency treatment to drain the accumulated blood. When a significant amount of blood collects at the surgical site it is called a “hematoma” and will likely need return to operating room be drained. Hematoma can occur at any time following surgery or any form of injury to the breast and may contribute to infection or other problems. It is very important to stay off all blood thinning medications for two weeks before and after surgery. Do not take aspirin or any anti-inflammatory medications before or after surgery, as this may increase the risk of bleeding. Non-prescription “herbs” and dietary supplements can increase the risk of surgical bleeding. Vitamin E, untested supplements, a variety of other prescription and over the counter medications should be avoided. After surgery, the risk of bleeding can

be reduced significantly by not straining or exerting yourself for at least four weeks, and by keeping your arms at your sides as much as possible for that period. Small amounts of bleeding can be absorbed by the body but can still impact healing.

Infection: Bacteria live on the skin and within the ducts of the breast. You will be given antibiotics through your intravenous line at the time of surgery and will require to take oral antibiotics following surgery. Although infection is unusual after this type of surgery, it may appear in the immediate post-operative period or at any time following the procedure. Should an infection occur, treatment including antibiotics, possible drainage, or additional surgery may be necessary.

Seroma: Fluid may accumulate around the implant following surgery, trauma, or vigorous exercise. Additional treatment may be necessary to drain fluid accumulation around breast or fat donor areas. This may contribute to infection or other problems.

Asymmetry: It is unusual to find a person with perfectly symmetric breasts. Because the body is not completely symmetric and most people have a dominant upper extremity, there is usually a small amount of asymmetry following this type of surgery. Differences in terms of breast and nipple shape, size, or symmetry may also occur after surgery. These small degrees of asymmetry need to be accepted. Large degrees of asymmetry may be improved with additional surgery.

Calcification, cysts and swellings: Calcium deposits can form in and around the areas of fat graft which did not take up. In mammography, these can present as thin walled calcifications around oil cysts or coarse irregular calcifications. These can usually be differentiated from clusters of pleomorphic calcifications, which occur in early breast cancer. On ultrasound examination, liponecrotic cysts often appear as anechoic areas. On MRI, necrotic area of fat has lower signal intensity than normal fat. With the help of these investigations, the persistent areas of fat necrosis can usually be differentiated from breast cancer. However, in cases of persistent symptoms and inability to differentiate, additional surgery may be necessary to remove and examine these areas.

Pain: Expect some pain and discomfort for around one month. This will improve gradually. Severe pain is not expected, and you should present yourself for examination if there is a problem. Gentle massage may help alleviate pain in fat donor area.

Change in Nipple and Skin Sensation: Nerves that provide sensation to the nipple come from branches through the ribs and around the side of the breast. During the procedure, these nerves may be stretched, and sometimes even cut. Uncommonly, people will experience a decrease in nipple sensation following this type of surgery, although some become hypersensitive. It may take a year before maximal return is seen. In rare cases, nipple numbness can be permanent.

Risk of cancer: Autologous fat grafting to breast is not known to stimulate cancerous growth in the breast. In-fact this surgery is also carried out in some biologic women, who have undergone resection for breast cancer. Studies also show an increased risk of breast cancer in trans women compared with cisgender men, probably due to the feminizing hormone

therapy. Therefore, transwomen undergoing autologous fat augmentation of breasts should undergo regular follow-up for monitoring as advised by the physician, including MRI and mammograms. The absolute overall risk of breast cancer in transgender people remains low and therefore it seems sufficient for transgender people using hormone treatment to follow screening guidelines as for cisgender women.

Problems with Healing: Wound disruption or delayed wound healing is possible. Some areas of the breast skin or nipple region may not heal normally and may take a long time to heal. Risk factors for tissue breakdown or necrosis include a depressed immune system, steroid use, smoking, history of radiation, and exposure to extreme temperatures. The incision sites may become hypertrophic. Bruising, hyperpigmentation and unevenness may persist in the donor area. Smokers have a greater risk of wound healing complications.

S**utures:** Incisions are likely to be small, typically less than one cm. These may or may not be sutured as per the surgeon preference and situation. You may notice these sutures after your surgery. Sutures may spontaneously poke through the skin, become visible or produce irritation that requires suture removal.

Poor Appearing Scars: All surgery leaves permanent scars. In some cases, these are more visible than others. Although a normal wound healing is expected after a surgical procedure, sometimes abnormal scars/keloid may occur within the skin and deeper tissues. There are many things that you will be required to do and be advised after surgery to improve the appearance of the scars. These may include application of various creams, gels, gel sheets, pressure garments and intra scar injections. It may take upto a year for the final/ long term appearance of scars to emerge. Surgery for scar revision may rarely be required.

Stretch marks: Individuals on feminizing hormonal therapy have higher propensity for developing stretch marks on the breast skin which might be dark colored. It might settle with time; however complete resolution of the stretch marks is unusual.

Dissatisfaction with Cosmetic Results: The lipoinjection volume for your surgery will be decided according to how much breast tissue you have, the ptosis, the size of your rib cage, laxity of your skin, your body shape, and finally, your target cup size. The take of injected fat graft is variable. Typically, around 40-60% of fat graft takes, and the remaining fat absorbs or necroses. You may require multiple sittings to achieve your target cup size. The augmentation with this method is at most one cup size or moderate. If you desire significant augmentation of more than a cup size, then you should look for alternate technique such as implant augmentation.

Risks of Surgery and Anesthesia: There are additional risks associated with having surgery, including medication reactions, and complications from anesthesia. Both local and general anesthesia involve risk. There is the possibility of complications, injury, and even death from all forms of surgical anesthesia or sedation. Other risks include pneumonia, deep venous thrombosis (blood clot in the leg), and pulmonary embolus (clot and rarely fat that travels to the lung), and allergic reactions. In rare cases, local allergies to tape, suture material and glues, blood products, topical preparations or injected agents have been reported. Serious

systemic reactions including anaphylaxis may occur in response to drugs used during surgery and prescription medicines. These are rare but are possible with any type of surgery.

Cardiac and Pulmonary Complications: Pulmonary complications may occur secondary to both blood clots (pulmonary emboli), fat deposits (fat emboli) or partial collapse of the lungs after general anesthesia. Pulmonary emboli can be life-threatening or fatal in some circumstances. Cardiac complications are a risk with any surgery and anesthesia, even in individuals without symptoms. Should any of these complications occur, you may require hospitalization and additional treatment. If you experience shortness of breath, chest pains, or unusual heart beats after surgery, seek medical attention immediately.

Photographs: Pre-operative and post-operative photos will be taken to help with surgical planning and to document results. Your photos (which never include your face) may also be used for teaching purposes to help doctors or other individuals.

Long-Term Results: Subsequent alterations in breast shape may occur as the result of aging, weight loss, weight gain, or other circumstances not related to your augmentation mammaplasty. Breast sagginess after augmentation may normally occur.

INDIVIDUAL COMPLIANCE

Preoperatively, feminizing hormone therapy should be withheld for a period as advised by the endocrinologist/ physician.

Post operatively, follow all physician instructions carefully; this is essential for the success of your outcome. It is important that the surgical incisions are not subjected to excessive force, swelling, abrasion, or motion during the time of healing. Personal and vocational activity needs to be restricted. Protective dressings and drains should not be removed unless instructed by your plastic surgeon.

Successful post-operative function depends on both surgery and subsequent care. Physical activity that increases your pulse or heart rate may cause bruising, swelling, fluid accumulation and the need for return to surgery. It is wise to refrain from intimate physical activities after surgery until your physician states it is safe. It is important that you participate in follow-up care like topical applications, massage therapy, pressure garments, wearing supportive bra etc. You should return for postoperative checks and aftercare, and thus actively promote your recovery after surgery.

FINANCIAL RESPONSIBILITIES

The cost of surgery involves several charges for the services provided. The total includes infacility charges, fees charged by your surgeon, the cost of surgical supplies, anaesthesia, laboratory tests, and miscellaneous hospital charges, depending on where the surgery is performed. You will be provided an approximate written estimate of charges before surgery. Depending on whether the cost of surgery is covered by an insurance plan, you will be responsible for necessary co-payments, deductibles, and charges not covered.

The fees charged for this procedure do not include-

1) Charges after the discharge such as consults and dressings.
2) Charges for medicines, gels, ointments, gel-sheets, pressure garments, supporting bra etc.

3) Any potential future costs for additional procedures that you elect to have or require to revise, optimize, or complete your outcome.
4) Additional costs may occur should complications develop from the surgery. Secondary /additional surgeries, investigations or hospital stay, and surgery charges involved with revision surgeries would also be your responsibility.
5) The costs for physiotherapy or any supportive therapy if required.

CONSENT FOR SURGERY / PROCEDURE or TREATMENT

1. I hereby authorize Dr _____ and such assistants as may be selected to perform the following procedure or treatment**: AUGMENTATION MAMMOPLASTY with autologous fat injections.**
2. I recognize that during the surgical procedure and medical treatment or anaesthesia, unforeseen conditions may necessitate different procedures than those specified above. I therefore authorize the above physician and assistants or designees to perform such other procedures that are in the exercise of his or her professional judgment necessary and desirable. The authority granted under this paragraph shall include all conditions that require treatment and are not known to my physician at the time the procedure is begun.
3. I consent to the administration of such anaesthetics considered necessary or advisable. I understand that all forms of anaesthesia involve risk and the possibility of complications, injury, and sometimes death.
4. I understand what my surgeon can and cannot do, and I understand there are no warranties or guarantees, implied or specific about my outcome. I have had the opportunity to explain my goals and understand which desired outcomes are realistic and which are not. All my questions have been answered, and I understand the inherent (specific) risks of the procedures I seek, as well as those additional risks and complications, benefits, and alternatives. Understanding all of this, I elect to proceed.
5. I consent to be photographed or televised before, during, and after the operation(s) or procedure(s) to be performed, including appropriate portions of my body, for medical, scientific or educational purposes, provided my identity is not revealed by the pictures.
6. For purposes of advancing medical education, I consent to the admittance of observers to the operating room.
7. I consent to the utilization of blood products should these be deemed necessary by my surgeon and/or his/her appointees, and I am aware that there are potential significant risks to my health with their utilization.
8. I understand that the surgeon's fees are separate from the anaesthesia and hospital charges, and the fees are agreeable to me. If a secondary procedure is necessary, further expenditure will be required.
9. I realize that not having the operation is an option.
10. The procedure has been explained to me in a way that I understand**:**
    1. The above treatment or procedure to be undertaken
    2. There may be alternative procedures or methods of treatment
    3. There are risks to the procedure or treatment proposed

I consent to the treatment or procedure and the above listed items (1-10). I have fully discussed all aspects of the procedure, possible complication, aftercare, need for additional/ secondary/ revisional procedures and expenses to my satisfaction.

Name of Individual……Signature of Pt……

Date……

Name of the Witness……

Relationship……

Signature of witness……

Date……

Name of doctor……

Designation……

Signature……

Date……

2) INDIVIDUAL INFORMATION AND INFORMED CONSENT FOR FEMINIZING GENITOPLASTY INCORPORATING ILEAL SEGMENT

While many gender-incongruent individuals find comfort with their gender identity, role, and expression without surgery, for many others surgery is essential and medically necessary to alleviate their gender incongruence. For the latter group, relief from gender incongruence cannot be achieved without modification of their primary and/or secondary sex characteristics to establish greater congruence with their gender identity and expression. Vaginal, clitoral, labial and vestibular reconstruction is of major importance for the psychological and sexual well-being and quality of life in transgender women. The advantages of intestinal vaginoplasty are providing sufficient vaginal depth, self-lubricating, and a lesser tendency to shrink.

This is an informed-consent document that has been prepared to help inform you about male to female sex reassignment genital surgery, its risks, and alternative treatments. This document consists of two parts- the first part is detailed information regarding the procedure and the next is procedure specific consent. Please go through the entire document before consenting to the procedure.

Part 1- Individual information

Introduction

1) **Preconditions for surgery:**
   a) Firm diagnosis of Gender Incongruence, as per ICD-11/ DSM5 by two different mental health professionals.
   b) The reference letters from mental health professionals should include the parameters as mentioned in 7th SOCs, mainly the diagnosis, individual's mental competence to give consent for surgery and hormone therapy and the fact that all co-existing mental health conditions are currently well controlled.
   c) The individual has completed 12 months of hormone therapy under guidance from a hormone specialist/ gender team unless individual is unwilling to take hormones/ unable to take hormones or the hormone therapy is medically contraindicated. (In India many individuals, especially MTF, are however well adapted in their desired gender role and are unwilling to take hormone therapy).
   d) The individual has experienced living in desired gender role for a period of 12 months.
   e) A legally notarized waiver of liability affidavit on stamp paper, waiving the gender team's liability for removing individual's healthy organs, permanent loss of current sexual functioning and reproductive ability.

2) **Preoperative Requirements:**
   a) Stopping health supplements such as omega, fish oils, herbal products, garlic, green tea etc from 2 weeks prior to surgery.
   b) Stop smoking from 4 weeks prior to surgery.
   c) Limit/ stop alcohol intake 4 weeks prior to surgery.
   d) Hormone therapy should be stopped/ adjusted for 3-4 weeks prior to surgery as per advice of treating physician.
   e) Stop blood thinners if feasible, from 5 days prior to surgery with permission from individual's cardiologist.
   f) Liquid diet from 48 hours prior to surgery. Clear liquids only on the day prior to surgery.
   g) Bowel wash will be started 1pm on the day prior to surgery.

3) **Pre-operative Investigations:**
   a) Complete blood counts, coagulation profile, Blood sugar fasting and PP, LFT, RFT, TSH, viral markers for hepatitis B, C and HIV, EKG, Chest x ray. Ultrasound whole abdomen. Other specific investigations if required for co-existing conditions and as per current guidelines.

4) **Options for the proposed surgical procedure and details**

   Other surgical options are penile and augmenting flaps lined vaginoplasty, skin graft vaginoplasty, sigmoid segment vaginoplasty and peritoneal vaginoplasty. The pros and cons of all the options have been explained. In these cases, the method/ tissue for lining the neovaginal cavity is different. Most other steps are similar.

Another alternative could be to opt for reconstruction of only external organs, without creating a vaginal cavity.

5) <u>Procedure specific information:</u>

a) General individual identifiers, names of admitting surgeons, individual's and witness's signatures, permission for photo and videography etc are usually part of general hospital consent and also may be a part of this consent. Higher risk due to some co-existing condition and anaesthesia consents are separate.
b) Trimming of hair / Shaving of the private parts and abdomen will be done.
c) The procedure will be laparoscopic with or without a short abdominal incision in addition to laparoscopic ports.
d) The average duration of surgery is expected to be around 7-8 hours. It can vary in the individual case.

6) <u>Surgical Technique</u>

The procedure as described below may be varied and all steps may not be carried out. If needed, extra steps may be carried out and the procedure may be varied from the below description if operative situation so demands or as per surgeon's discretion.

1. The individual is placed in the lithotomy position laparoscopy ports are inserted. A suitable segment of ileum is mobilized, and mesentery is inspected for vascular pattern (under transillumination in fatty mesentery). Part of ileum will be isolated depending on the vascular pattern.
2. The segment of the ileum is divided at proximal and distal sites. The proximal end of the flap is closed making it the dome of neo-vagina.
3. Vaginal cavity (pelvic and perineal dissection): Cavity for future neo vagina is created between bladder and rectum by sharp and blunt pelvic dissection. About 1 cm from anus, a posteriorly based perineal/scrotal flap is raised and a cavity is created between urethral bulb and rectum. The perineal and pelvic parts of dissection are connected with careful bimanual palpation and dissection.
4. The ileal loop is delivered gently in the created cavity avoiding any kink of the pedicle. The distal end of the ileum is sutured with invaginated penile and scrotal flaps. The abdominal surgeon performs the ileal anastomosis. The abdomen is closed in layers.
5. Bilateral Orchiectomy: Both testes are removed. Cords may also be removed, or cord tissue may be used to augment labia majora as per requirement.
6. Penile skin degloving: Penile skin is degloved superficial to Buck's fascia all the way except a small flap of inner preputial skin which is left attached to the glans for purpose of forming clitoral hood.
7. Dissection of glanulo-preputial island flap: The dorso-lateral part of glans with attached preputial skin flap, underlying neurovascular bundles, with or without Bucks fascia and dorsal tunica albuginea is dissected, till the base of penis. The glans wings are sutured to themselves to create the neo clitoris.
8. Corpora are separated from urethra till just under the pubic symphysis, transected and resected.
9. Urethra is dissected to base, the bulbocavernosus muscle is removed to expose bare bulb. If the urethra is not being used for augmentation of penile skin flap,

excess urethra is removed and the opening in bulb is widened. The margins are everted to form new urinary meatus.

10. Slit is made in proximal part of penile skin flap for exposing the neoclitoris and urethral meatus. These structures are now sutured in place.
11. The distal end of penile skin flap is sutured to anterior edge of ileal segment in a staggered manner.
12. Remnants of scrotal skin flaps are sutured to penile skin flap, to form labia majora. Medial aspects of penile skin flaps around the slits may be fashioned to form labia minora.
13. A pack is usually placed in neovaginal cavity to maintain it. A dressing is then applied.

7) <u>Postoperative Course:</u>

At the end of operation, you will have:

1. Dressing over the perineum and left abdomen
2. Urinary catheter
3. Epidural catheter
4. Blood pressure cuff over the arm to measure your blood pressure (you will feel pressure over the arm intermittently)
5. Pulse Oximeter to monitor your pulse rate and oxygen saturation
6. DVT pump over lower limbs, you will feel intermittent pressure over the lower limbs. Usually kept for initial 24 to 48 hrs to prevent clotting in the leg veins.
7. Intravenous cannula- to administer antibiotics, IV fluids and other medicines.
8. Need for post op procedures- like dressings, dilation, drain removal and urinary catheter removal (catheter may be reinserted in case of urinary retention and may be kept for couple of weeks)
9. Position change---gentle guided side-turn allowed after 24 hrs.
10. Ambulation- usually 3rd to 7th day.
11. Dilation -dilation is usually started on 5th to 7th day.
12. Diet- You will be kept nil orally till the wind breaks (passing flatus). Once you pass flatus, you will be given clear fluid followed by liquid diet. Liquid to very soft diet is recommended till 4 weeks. After that you can resume normal diet.
13. Duration of hospital stay—7 to 10 days

8) <u>Complications</u> –

Note: The listed risks and complications are not all inclusive.

While majority of individuals have an uneventful surgery and recovery, few cases may be associated with complications. These are seen infrequently and not all the ones listed below are applicable to one individual. However, it is important that you are aware of the complications/risks that may arise out of this procedure which are as below:

a) Bleeding- It is possible, though unusual, to experience a bleeding episode during or after surgery. Should post-operative bleeding occur, it may require emergency treatment to drain accumulated blood or blood transfusion. You should reveal all the medications that you have been taking to the surgeon so that medicines that can cause bleeding can be stopped or its dose adjusted before the surgery.

b) Infection- Bacteria live on the skin and near the perineal area. You will be given antibiotics through your I.V. at the time of surgery and will be required to take oral antibiotics following surgery and after discharge. Although infection is unusual after this type of surgery, it may appear in the immediate post-operative period or at any time following the surgery. Should an infection occur, treatment including antibiotics, or additional surgery may be necessary.

c) Vascular compromise- though rare, there are chances of failure of operation due to vascular problems of ileum. If so, then one of the alternate procedures as detailed above may be required.

d) Injury to nearby structures- urethra (1.2 %), ureters, bladder and rectum (2.3 %-2.5 %) leading to Recto vaginal fistulas (0.6 %- 1.1 %) or urethra neovaginal fistula (1.7 %-2 %)

e) Necrosis - clitoro-labial complex partial or complete (0.5 % -24 %)

f) Paralytic ileus and bowel obstruction can occur (0.8 %-3.6 %) which may necessitate prolonged fasting and nasogastric aspiration, and in some cases repeat surgery.

g) Altered bowel habits might occur

h) Urinary issues (retention/incontinence/infection (1.3 %-14 %). Urethral meatus stenosis might occur which might need dilatation and possibly surgery

i) Mucorrhea- Excessive mucus discharge (6.2 %-28.6 %) might occur

j) Prolapse of the ileal segment might occur. (1.5 %)

k) Corpus spongiosum protrusion- (6.1 %-15.6 %)

l) Introital or Vaginal stenosis (1.5 %- 22.5 %)

m) Decreased/absent sensations with possible absence of orgasmic capabilities (3.3 %)

n) Wound healing issues (5.4 %)

o) Scarring/hypertrophic scar/keloid over abdomen and perineum

p) Ileal anastomotic leak with possible need for creation of a stoma(ileostomy or colostomy).

q) Abdominal hernia

r) Possible Touch up procedures/surgical corrections (for aesthetic improvement, vaginal stenosis, corpus spongiosum correction etc.

s) Pulmonary embolism—sometimes blood clot in the leg vein can travel up to lungs and cause difficulty in breathing. We use DVT pump and proper IV fluids to prevent. But rarely, deaths have been reported

t) The procedure is irreversible. There will be permanent loss of ability to serve as a male partner in penetrative sexual intercourse.

u) **There will be loss of fertility due to removal of testes. This procedure will not grant you the ability to conceive.**

v) The procedure in itself does not provide any guarantees to you about successful sexual intercourse or success in marriage or relationship.

w) **Unsatisfactory result**- You may be disappointed with the result of the surgery. It may be necessary to perform additional surgery to improve your results.

x) **Allergic reactions**- In rare cases, local allergies to tape, suture material, or topical preparations have been reported. Systemic reactions which are more serious may occur to drugs used during surgery and prescription medicines. Allergic reactions may require additional treatment.

y) **Surgical anaesthesia**- Both local and general anaesthesia involve risk. There is the possibility of complications, injury, and even death from all forms of surgical anaesthesia or sedation.

z) **Additional surgery necessary-** There are many variable conditions that may influence the long-term result of male to female genital gender affirmation surgery. Should complications occur, additional surgery or other treatments may be necessary. Besides the cited complications, other complications and risks can occur but are even more uncommon. The practice of medicine and surgery is not an exact science. Although good results are expected, there is no guarantee or warranty expressed or implied, on the results that may be obtained.

9) **Discharge instructions- vary individual to individual and will be explained to you at the time of discharge.**

10) **Post-operative follow-up**

Special precautions to be taken at home

a) Diet- liquid to soft diet for 4 weeks.
b) Local cleaning and dressing as explained. Need to wear a clean pad.
c) Have bath regularly.
d) Dilation schedule to be followed as instructed for at least 6 months, and later on if required.
e) Exercise and Sexual activities- usually after 8 weeks
f) Scar care explained.
g) Urinary catheter care if individual is discharged with catheter and need of catheter removal in local area or during follow up
h) Possible need of touch procedures explained

Follow up every month till 6 months, at follow up special focus on dilation.

Follow up with Psychiatrist/psychologist and Endocrinologist as per their advice.

Financial responsibilities

The cost of surgery involves several charges for the services provided. The total includes fees charged by your doctor, the cost of surgical supplies, laboratory tests, blood bank, anaesthesia, and hospital charges, depending on where the surgery is performed. Depending on whether the cost of surgery is covered by an insurance plan, you will be responsible for necessary co-payments, deductibles, and charges not covered.

Additional costs may occur should complications develop from the surgery. Secondary /additional surgeries, investigations or hospital stay and surgery charges involved with revision surgeries would also be your responsibility.

PART 2- CONSENT FORM

DISCLAIMER

Informed-consent documents are used to communicate information about the proposed surgical treatment of a disease or condition along with disclosure of risks and alternative

forms of treatment(s). The informed-consent process attempts to define principles of risk disclosure that should generally meet the needs of most individuals in most circumstances.

However, informed consent documents should not be considered all-inclusive in defining other methods of care and risks encountered. Your plastic surgeon may provide you with additional or different information which is based on all the facts in your particular case and the state of medical knowledge.

Informed-consent documents are not intended to define or serve as the standard of medical care. Standards of medical care are determined on the basis of all of the facts involved in an individual case and are subject to change as scientific knowledge and technology advance and as practice patterns evolve.

CONSENT FOR SURGERY / PROCEDURE or TREATMENT

a) I hereby authorize Dr _____ and such assistants as may be selected to perform the following procedure or treatment**: feminizing genitoplasty with incorporation of ileal segment for lining the neovaginal cavity.**
b) I consent to the presence of OR staff of either sex to be present in OR during my surgery. I understand that they are present for the safe conduct of my surgery.
c) I recognize that during the course of the operation and medical treatment or anesthesia, unforeseen conditions may necessitate different procedures than those above. I therefore authorize the above physician and assistants or designees to perform such other procedures that are in the exercise of his or her professional judgment necessary and desirable. The authority granted under this paragraph shall include all conditions that require treatment and are not known to my physician at the time the procedure is begun.
d) I consent to the administration of such anaesthetics considered necessary or advisable. I understand that all forms of anaesthesia involve risk and the possibility of complications, injury, and sometimes death.
e) I understand what my surgeon can and cannot do, and I understand there are no warranties or guarantees, implied or specific about my outcome. I have had the opportunity to explain my goals and understand which desired outcomes are realistic and which are not. All of my questions have been answered, and I understand the inherent (specific) risks of the procedures I seek, as well as those additional risks and complications, benefits, and alternatives. Understanding all of this, I elect to proceed.
f) I consent to be photographed or televised before, during, and after the operation(s) or procedure(s) to be performed, including appropriate portions of my body, for medical, scientific or educational purposes, provided my identity is not revealed by the pictures.
g) For purposes of advancing medical education, I consent to the admittance of observers to the operating room.
h) I consent to the utilization of blood products should they be deemed necessary by my surgeon and/or his/her appointees, and I am aware that there are potential significant risks to my health with their utilization.
i) I understand that the surgeon's fees are separate from the anaesthesia and hospital charges, and the fees are agreeable to me. If a secondary procedure is necessary, further expenditure will be required.

j) I realize that not having the operation is an option. **I understand that no guarantee has been made that the procedure will improve the condition and that the procedure may make my condition worse.**

k) It has been explained to me in a way that i understand**:**
   a. The above treatment or procedure to be undertaken
   b. There may be alternative procedures or methods of treatment
   c. There are risks to the procedure or treatment proposed

I consent to the treatment or procedure. I am satisfied with the explanation.

Name of Individual……Signature of Pt……..……

Date……

Name of the Witness……

Relationship……..

Signature of witness……

Date……

Name of doctor……

Designation……..……

Signature…….. Date……..

3) INDIVIDUAL INFORMATION AND INFORMED CONSENT FOR FEMINIZING GENITOPLASTY INCORPORATING PENILE SKIN FLAP AUGMENTED WITH PERINEAL- SCROTAL SKIN FLAPS FOR VAGINAL LINING

GENERAL INFORMATION

While many gender-incongruent individuals find comfort with their gender identity, role, and expression without surgery, for many others surgery is essential and medically necessary to alleviate their gender incongruence. For the latter group, relief from gender incongruence cannot be achieved without modification of their primary and/or secondary sex characteristics to establish greater congruence with their gender identity and expression. Vaginal, clitoral, labial and vestibular reconstruction is of major importance for the psychological and sexual well-being and quality of life in transgender women. Advantages of the procedure are less shrinkage compared to skin graft, no need of an abdominal procedure, no need of bowel surgery and hence, less morbidity and attainment of good vaginal depth.

This is an informed-consent document that has been prepared to help inform you about male to female gender affirming genital surgery, its risks, and alternative treatments. This document consists of two parts- the first part is detailed information regarding the procedure and the next is procedure specific consent. Please go through the entire document before consenting to the procedure.

Part 1- Individual information

Introduction

1) **Preconditions for surgery:**
   a) Firm diagnosis of Gender Incongruence, as per ICD-11/ DSM5 by two different mental health professionals.
   b) The reference letters from mental health professionals should include the parameters as mentioned in 7th SOCs, mainly the diagnosis, individual's mental competence to give consent for surgery and hormone therapy and the fact that all co-existing mental health conditions are currently well controlled.
   c) The individual has completed 12 months of hormone therapy under guidance from a hormone specialist/ gender team unless individual is unwilling to take hormones/ unable to take hormones or the hormone therapy is medically contraindicated. (Many individuals in India, especially MTF, are however well adapted in their desired gender role and are unwilling to take hormone therapy).
   d) The individual has experienced living in desired gender role for a period of 12 months.
   e) A legally notarized waiver of liability affidavit on stamp paper, waiving the gender team's liability for removing individual's healthy organs, permanent loss of current sexual functioning and reproductive ability.

2) **Preoperative Requirements:**
   a) Stopping health supplements such as omega, fish oils, herbal products, garlic, green tea etc from 2 weeks prior to surgery.
   b) Stop smoking from 4 weeks prior to surgery.
   c) Limit/ stop alcohol intake 4 weeks prior to surgery.
   d) Hormone therapy should be stopped/ adjusted for 3-4 weeks prior to surgery as per advice of treating physician.
   e) Stop blood thinners if feasible, from 5 days prior to surgery with permission from individual's physician/ cardiologist.

3) **Pre-operative Investigations:**
   Complete blood counts, coagulation profile, Blood sugar fasting and PP, LFT, RFT, TSH, viral markers for hepatitis B, C and HIV, EKG, Chest x ray. Other specific investigations if required for co-existing conditions and as per current guidelines.

4) **Alternative Options for the proposed surgical procedure**
   Other surgical options are skin grafting, ileal vaginoplasty, sigmoid segment vaginoplasty and peritoneal vaginoplasty. In these cases, the method/ tissue for lining the neovaginal cavity is different. Most other steps are similar. Another alternative could be to opt for reconstruction of only external organs, without creating a vaginal cavity.

5) **Procedure specific information:**
   a) General individual identifiers, names of admitting surgeons, individual's and witness's signatures, permission for photo and videography etc are usually part of

general hospital consent and, also may be a part of this consent. Higher risk due to some co-existing condition and anaesthesia consents are separate.

b) Trimming of hair / Shaving of the private parts and abdomen will be done.

c) The average duration of surgery is expected to be around 4-5 hours. It can vary in the individual case.

d) <u>Surgical Technique</u>

The procedure as described below may be varied and all steps may not be carried out. If needed, extra steps may be carried out and the procedure may be varied from the below description if operative situation so demands or as per operating surgeon's discretion.

i) The individual is placed in the lithotomy position.

ii) Bilateral Orchiectomy: Both testes are removed. Cords may also be removed, or cord tissue may be used to augment labia majora as per requirement.

iii) Penile skin degloving: Penile skin is degloved superficial to Buck's fascia all the way except a small flap of inner preputial skin which is left attached to the glans for purpose of forming clitoral hood.

iv) Dissection of glanulo-preputial island flap: The dorso-lateral part of glans with attached preputial skin flap, underlying neurovascular bundles, with or without Bucks fascia and dorsal tunica albuginea is dissected, till the base of penis. The glans wings are sutured to themselves to create the neo clitoris.

v) Corpora are separated from urethra till just under the pubic symphysis, transected and resected.

vi) Urethra is dissected to base, the bulbocavernosus muscle is removed to expose bare bulb. If the urethra is not being used for augmentation of penile skin flap, excess urethra is removed and the opening in bulb is widened. The margins are everted to form new urinary meatus.

vii) Vaginal cavity (pelvic and perineal dissection): Cavity for future neo vagina is created between bladder and rectum by sharp and blunt pelvic dissection.

viii) Additional vaginal cavity lining flaps: Additional flaps may be dissected from central perineal skin, scrotum and/or urethra to augment the penile skin flap in order to create a deeper lined vaginal cavity.

ix) Penile skin flap is now used on it's own, or joined to scrotal flap/ perineal flap/ urethral flap/ scrotal skin graft to create vaginal lining.

x) Slit is made in proximal part of penile skin flap for exposing the neoclitoris and urethral meatus. These structures are now sutured in place.

xi) Suture may taken from penile skin flap to either one or both sacrospinous ligaments for preventing postoperative vaginal prolapse. The neovaginal lining is now inserted into dissected cavity and sacrospinous ligament sutures tied.

xii) Remnants of scrotal skin flaps are sutured to penile skin flap, to form labia majora. Medial aspects of penile skin flaps around the slits may be fashioned to form labia minora.

xiii) A pack is usually placed in neovaginal cavity to maintain it. A dressing is then applied.

6) **Postoperative Course:**

At the end of operation, you will have:

a) Dressing over the perineum.
b) Urinary catheter
c) Epidural catheter
d) Blood pressure cuff over the arm to measure your blood pressure (you will feel pressure over the arm intermittently)
e) Pulse Oximeter to monitor your pulse rate and oxygen saturation
f) DVT pump over lower limbs, you will feel intermittent pressure over the lower limbs. Usually kept for initial 24 to 48 hrs to prevent clotting in the leg veins.
g) Intravenous cannula- to administer antibiotics, IV fluids and other medicines.
h) Need for post op procedures- like dressings, dilation, drain removal and urinary catheter removal (catheter may be reinserted in case of urinary retention and may be kept for couple of weeks)
i) Position change---gentle guided side-turn allowed after 24 hrs.
j) Ambulation- usually 3rd to 7th day.
k) Dilation -dilation is usually started on 5th to 7th day.
l) Duration of hospital stay—4-6 days

7) **Complications** –

Note: The listed risks and complications are not all inclusive.

While majority of individuals have an uneventful surgery and recovery, few cases may be associated with complications. These are seen infrequently and not all the ones listed below are applicable to one individual. However, it is important that you are aware of the complications/risks that may arise out of this procedure which are as below:

a) Bleeding- It is possible, though unusual, to experience a bleeding episode during or after surgery. Should post-operative bleeding occur, it may require emergency treatment to drain accumulated blood or blood transfusion. You should reveal all the medications that you have been taking to the surgeon so that medicines that can cause bleeding can be stopped or its dose adjusted before the surgery.

b) Infection- Bacteria live on the skin and near the perineal area. You will be given antibiotics through your I.V. line at the time of surgery and will be required to take oral antibiotics on discharge. Although infection is unusual after this type of surgery, it may appear in the immediate post-operative period or at any time following the surgery. Should an infection occur, treatment including antibiotics, or additional surgery may be necessary.
c) Vascular compromise- though rare, there are chances of failure of operation due to vascular problems of the penile or augmenting skin flap. If so, there may be loss

of vaginal depth. To restore vaginal depth, you may require alternative procedure at a later date.

d) Injury to nearby structures- urethra (1.2 %), ureters, bladder and rectum (2.3 %-2.5 %) leading to Recto vaginal fistulas (0.6 %- 1.1 %) or urethra neovaginal fistula (1.7 %-2 %) may occur.
e) There may be loss of blood supply to clitoro-labial complex partial or complete (0.5 % -24 %) resulting in necrosis and subsequent loss of these structures.
f) Urinary issues (retention/incontinence/infection (1.3 %-14 %). Urethral meatus stenosis might occur which might need dilatation and possibly surgery
g) Corpus spongiosum protrusion may occur in some cases leading to interference with vaginal intercourse- (6.1 %-15.6 %)
h) Introital or Vaginal stenosis (1.5 %- 22.5 %) may occur.
i) Decreased/absent sensations with possible absence of orgasmic capabilities may occur in around 3.3 % cases.
j) Wound healing issues may occur in around 5.4% cases leading to delayed healing.
k) Possible hair growth may occur in neovagina. This may require the use of epilating creams.
l) There may be chances of abnormal/ hypertrophic scarring, as in any surgery.
m) Possible Touch up procedures/surgical corrections may be required for aesthetic improvement and above conditions.
n) Pulmonary embolism—sometimes blood clots in the leg vein can travel up to lungs and cause difficulty in breathing. We use DVT pump and proper IV fluids to prevent. But rarely, deaths have been reported
o) The procedure is irreversible. There will be permanent loss of ability to serve as a male partner in penetrative sexual intercourse.
p) There will be permanent loss of fertility due to loss of testicles. This procedure will not grant you the ability to conceive.
q) The procedure in itself does not provide any guarantees to you about successful sexual intercourse or success in marriage or relationship success.
r) **Unsatisfactory result**- You may be disappointed with the result of the surgery. It may be necessary to perform additional surgery to improve your results.
s) **Allergic reactions**- In rare cases, local allergies to tape, suture material, or topical preparations have been reported. Systemic reactions which are more serious may occur to drugs used during surgery and prescription medicines. Allergic reactions may require additional treatment.
t) **Surgical anaesthesia**- Both local and general anaesthesia involve risk. There is the possibility of complications, injury, and even death from all forms of surgical anaesthesia or sedation.
u) **Additional surgery may be necessary-** There are many variable conditions that may influence the long-term result of male to female genital gender affirmation surgery. Should complications occur, additional surgery or other treatments may be necessary. Besides the cited complications, other complications and risks can occur but are even more uncommon. The practice of medicine and surgery is not an exact science. Although good results are expected, there is no guarantee or warranty expressed or implied, on the results that may be obtained.

8) **Discharge instructions- vary individual to individual and will be explained to you at the time of discharge.**

9) **Post-operative follow-up**

Special precautions to be taken at home

a) Local cleaning and dressing as explained. Need to wear a clean pad.
b) Have bath regularly.
c) Dilation schedule to be followed as instructed for at least 3 months, and to be continued later if required.
d) Exercise and Sexual activities may be permitted usually after 8 weeks
e) Initial wound and later scar care may be advised with specific topical applications.
f) Urinary catheter care if individual is discharged with catheter and need of catheter removal in local area or during follow up
g) Possible need of touch procedures explained

Follow-up may be required with decreasing frequency and increasing interval.

Follow up with Psychiatrist/psychologist and Endocrinologist as per their advice.

Financial responsibilities

The cost of surgery involves several charges for the services provided. The total includes fees charged by your doctor, the cost of surgical supplies, laboratory tests, blood bank, anaesthesia, and hospital charges, depending on where the surgery is performed. Depending on whether the cost of surgery is covered by an insurance plan, you will be responsible for necessary co-payments, deductibles, and charges not covered.

Additional costs may occur should complications develop from the surgery. Secondary /additional surgeries, investigations or hospital stay and surgery charges involved with revision surgeries would also be your responsibility.

PART 2- CONSENT FORM

DISCLAIMER

Informed-consent documents are used to communicate information about the proposed surgical treatment of a disease or condition along with disclosure of risks and alternative forms of treatment(s). The informed-consent process attempts to define principles of risk disclosure that should generally meet the needs of most individuals in most circumstances.

However, informed consent documents should not be considered all-inclusive in defining other methods of care and risks encountered. Your plastic surgeon may provide you with additional or different information which is based on all the facts in your particular case and the current state of medical knowledge.

Informed-consent documents are not intended to define or serve as the standard of medical care. Standards of medical care are determined on the basis of all of the facts involved in an

individual case and are subject to change as scientific knowledge and technology advance and as practice patterns evolve.

CONSENT FOR SURGERY / PROCEDURE or TREATMENT

a) I hereby authorize Dr _____ and such assistants as may be selected to perform the following procedure or treatment**: feminizing genitoplasty with use of penile skin flap augmented with perineal- scrotal skin flaps for lining the neovaginal cavity.**
b) I consent to the presence of OR staff of either sex to be present in OR during my surgery. I understand that they are present for the safe conduct of my surgery.
c) I recognize that during the course of the operation and medical treatment or anaesthesia, unforeseen conditions may necessitate different procedures than those above. I therefore authorize the above physician and assistants or designees to perform such other procedures that are in the exercise of his or her professional judgment necessary and desirable. The authority granted under this paragraph shall include all conditions that require treatment and are not known to my physician at the time the procedure is begun.
d) I consent to the administration of such anaesthetics considered necessary or advisable. I understand that all forms of anaesthesia involve risk and the possibility of complications, injury, and sometimes death.
e) I understand what my surgeon can and cannot do, and I understand there are no warranties or guarantees, implied or specific about my outcome. I have had the opportunity to explain my goals and understand which desired outcomes are realistic and which are not. All of my questions have been answered, and I understand the inherent (specific) risks of the procedures I seek, as well as those additional risks and complications, benefits, and alternatives. Understanding all of this, I elect to proceed.
f) I consent to be photographed or televised before, during, and after the operation(s) or procedure(s) to be performed, including appropriate portions of my body, for medical, scientific or educational purposes, provided my identity is not revealed by the pictures.
g) For purposes of advancing medical education, I consent to the admittance of observers to the operating room.
h) I consent to the utilization of blood products should they be deemed necessary by my surgeon and/or his/her appointees, and I am aware that there are potential significant risks to my health with their utilization.
i) I understand that the surgeon's fees are separate from the anaesthesia and hospital charges, and the fees are agreeable to me. If a secondary procedure is necessary, further expenditure will be required.
j) I realize that not having the operation is an option. **I understand that though it is expected to, but no guarantee has been made that the procedure will improve the condition and that the procedure may make my condition worse.**
k) It has been explained to me in a way that I understand**:**
    a. The above treatment or procedure to be undertaken
    b. There may be alternative procedures or methods of treatment
    c. There are risks to the procedure or treatment proposed

I consent to the treatment or procedure. I am satisfied with the explanation.

Name of Individual……Signature of Pt……

Date……

Name of the Witness……

Relationship……

Signature of witness……

Date……

Name of doctor……

Designation……

Signature…… Date……..

4) INDIVIDUAL INFORMATION AND INFORMED CONSENT FOR FEMINIZING GENITOPLASTY INCORPORATING SIGMOID SEGMENT VAGINAL LINING

GENERAL INFORMATION

While many gender-incongruent individuals find comfort with their gender identity, role, and expression without surgery, for many others surgery is essential and medically necessary to alleviate their gender incongruence. For the latter group, relief from gender incongruence cannot be achieved without modification of their primary and/or secondary sex characteristics to establish greater congruence with their gender identity and expression. Vaginal, clitoral, labial and vestibular reconstruction is of major importance for the psychological and sexual well-being and quality of life in transgender women. The advantages of intestinal vaginoplasty are providing sufficient vaginal depth, self-lubricating, and a lesser tendency to shrink.

This is an informed-consent document that has been prepared to help inform you about male to female sex reassignment genital surgery, its risks, and alternative treatments. This document consists of two parts- the first part is detailed information regarding the procedure and the next is procedure specific consent. Please go through the entire document before consenting to the procedure.

Part 1- Individual information

Introduction

1) **Preconditions for surgery:**

a) Firm diagnosis of Gender Incongruence, as per ICD-11/ DSM5 by two different mental health professionals.

b) The reference letters from mental health professionals should include the parameters as mentioned in 7th SOCs, mainly the diagnosis, individual's mental competence to give consent for surgery and hormone therapy and the fact that all co-existing mental health conditions are currently well controlled.
c) The individual has completed 12 months of hormone therapy under guidance from a hormone specialist/ gender team unless individual is unwilling to take hormones/ unable to take hormones or the hormone therapy is medically contraindicated. (Many individuals in India, especially MTF, are however well adapted in their desired gender role and are unwilling to take hormone therapy).
d) The individual has experienced living in desired gender role for a period of 12 months.
e) A legally notarized waiver of liability affidavit on stamp paper, waiving the gender team's liability for removing individual's healthy organs, permanent loss of current sexual functioning and reproductive ability.

2) <u>Preoperative Requirements:</u>

a) Stopping health supplements such as omega, fish oils, herbal products, garlic, green tea etc from 2 weeks prior to surgery.
b) Stop smoking from 4 weeks prior to surgery.
c) Limit/ stop alcohol intake 4 weeks prior to surgery.
d) Hormone therapy should be stopped/ adjusted for 3-4 weeks prior to surgery as per advice of treating physician.
e) Stop blood thinners if feasible, from 5 days prior to surgery with permission from individual's physician/cardiologist.
f) Liquid diet from 48 hours prior to surgery. Clear liquids only on the day prior to surgery.
g) Bowel wash will be started 1pm on the day prior to surgery.

3) <u>Pre-operative Investigations:</u>

Complete blood counts, coagulation profile, Blood sugar fasting and PP, LFT, RFT, TSH, viral markers for hepatitis B, C and HIV, EKG, Chest x ray, Ultrasound whole abdomen. Other specific investigations if required for co-existing conditions and as per current guidelines.

4) **<u>Options for the proposed surgical procedure and details</u>**

Other surgical options are penile and augmenting flaps lined vaginoplasty, skin graft vaginoplasty, ileal segment vaginoplasty and peritoneal vaginoplasty. The pros and cons of all the options have been explained. In these cases, the method/ tissue for lining the neovaginal cavity is different. Most other steps are similar. Another alternative could be to opt for reconstruction of only external organs, without creating a vaginal cavity.

5) <u>Procedure specific information:</u>

a) General individual identifiers, names of admitting surgeons, individual's and witness's signatures, permission for photo and videography etc are usually part of general hospital consent and, also may be a part of this consent. Higher risk due to some co-existing condition and anaesthesia consents are separate.
b) Trimming of hair / Shaving of the private parts and abdomen will be done.

c) Location and length of incision and future scar- The procedure will be laparoscopic with or without a short lower abdomen transverse incision. Sometimes the incision will be made in the Left lower abdomen (left Pfannenstiel) or midline incision (open approach). At the end of the surgery, stitches are applied which are removed after 10-15 days.
d) The average duration of surgery is expected to be around 7-8 hours. It can vary in the individual case.

6) <u>Surgical Technique</u>

The procedure as described below may be varied and all steps may not be carried out. If needed, extra steps may be carried out and the procedure may be varied from the below description if operative situation so demands.

a) The individual is placed in the lithotomy position and an open or a laparoscopic approach is used. Recto-sigmoid colon is mobilized, and mesentery is inspected for vascular pattern (under transillumination in fatty mesentery). Part of rectosigmoid colon will be isolated based either on proximal or on distal pedicle depending on the vascular pattern.
b) The segment of the colon is divided at proximal and distal sites. The proximal end of graft is closed (distal end in cases of distal pedicle) making it the dome of neo-vagina.
c) Vaginal cavity (pelvic and perineal dissection): Cavity for future neo vagina is created between bladder and rectum by sharp and blunt pelvic dissection. About 1 cm from anus, a posteriorly based triangular perineal/scrotal skin flap (4 cm base width x 6 cm length) is raised and a cavity is created between urethral bulb and rectum. The perineal and pelvic parts of dissection are joined with careful bimanual palpation and dissection.
d) The colon graft is delivered gently in the created cavity avoiding any kink of the pedicle. The distal end of the colon is sutured with invaginated perineal-scrotal flap completing posterior vaginal wall. The abdominal surgeon performs the colon anastomosis. An abdominal drain is placed (surgeon's decision as per requirement) and the abdomen is closed in layers.
e) Bilateral Orchiectomy: Both testes are removed. Cords may also be removed, or cord tissue may be used to augment labia majora as per requirement.
f) Penile skin degloving: Penile skin is degloved superficial to Buck's fascia all the way except a small flap of inner preputial skin which is left attached to the glans for purpose of forming clitoral hood.
g) Dissection of glanulo-preputial island flap: The dorso-lateral part of glans with attached preputial skin flap, underlying neurovascular bundles, with or without Bucks fascia and dorsal tunica albuginea is dissected, till the base of penis. The glans wings are sutured to themselves to create the neo clitoris.
h) Corpora are separated from urethra till just under the pubic symphysis, transected and resected.
i) Urethra is dissected to base, the bulbocavernosus muscle is removed to expose bare bulb. If the urethra is not being used for augmentation of penile skin flap,

excess urethra is removed and the opening in bulb is widened. The margins are everted to form new urinary meatus.

j) Slit is made in proximal part of penile skin flap for exposing the neoclitoris and urethral meatus. These structures are now sutured in place.
k) The distal end of penile skin flap is sutured to anterior edge of sigmoid colon in a staggered manner.
l) Remnants of scrotal skin flaps are sutured to penile skin flap, to form labia majora. Medial aspects of penile skin flaps around the slits may be fashioned to form labia minora.
m) A pack is usually placed in neovaginal cavity to maintain it. A dressing is then applied.

7) <u>Postoperative Course:</u>

At the end of operation, you will have:

a) Dressing over the perineum and left abdomen
b) Urinary catheter
c) Abdominal drain
d) Epidural catheter
e) Blood pressure cuff over the arm to measure your blood pressure (you will feel pressure over the arm intermittently)
f) Pulse Oximeter to monitor your pulse rate and oxygen saturation
g) DVT pump over lower limbs, you will feel intermittent pressure over the lower limbs. Usually kept for initial 24 to 48 hrs to prevent clotting in the leg veins.
h) Intravenous cannula- to administer antibiotics, IV fluids and other medicines.
i) Need for post op procedures- like dressings, dilation, drain removal and urinary catheter removal (catheter may be reinserted in case of urinary retention and may be kept for couple of weeks)
j) Position change---gentle guided side-turn allowed after 24 hrs.
k) Ambulation- usually 3rd to 7th day.
l) Dilation -dilation is usually started on 3rd to 5th day.
m) Diet- You will be kept nil orally till the wind breaks (passing flatus). Once you pass flatus, you will be given clear fluid followed by liquid diet. Liquid to very soft diet is recommended till 4 weeks. After that you can resume normal diet.
n) Duration of hospital stay—7 to 10 days

8) <u>Complications</u> –

Note: The listed risks and complications are not all inclusive.

While majority of individuals have an uneventful surgery and recovery, few cases may be associated with complications. These are seen infrequently and not all the ones listed below are applicable to one individual. However, it is important that you are aware of the complications/risks that may arise out of this procedure which are as below:

a) Bleeding- It is possible, though unusual, to experience a bleeding episode during or after surgery. Should post-operative bleeding occur, it may require emergency treatment to drain accumulated blood or blood transfusion. You should reveal all the medications that you have been taking to the surgeon so that medicines that can cause bleeding can be stopped or its dose adjusted before the surgery.

b) Infection- Bacteria live on the skin and near the perineal area. You will be given antibiotics through your I.V. at the time of surgery and will be required to take oral antibiotics following surgery and after discharge. Although infection is unusual after this type of surgery, it may appear in the immediate post-operative period or at any time following the surgery. Should an infection occur, treatment including antibiotics, or additional surgery may be necessary.
c) Vascular compromise- though rare, there are chances of failure of operation due to vascular problems of sigmoid colon segment (0.5 %). If so, then one of the alternative procedures as detailed above may be required.
d) Injury to nearby structures- urethra (1.2 %), ureters, bladder and rectum (2.3 %-2.5 %) leading to Recto vaginal fistulas (0.6 %- 1.1 %) or urethra neovaginal fistula (1.7 %-2 %)
e) Necrosis - Clitoro-labial complex partial or complete (0.5 % -24 %) resulting in loss of these structures.
f) Paralytic ileus and bowel obstruction can occur (0.8 %-3.6 %) which may necessitate prolonged fasting and nasogastric aspiration, and in some cases repeat surgery.
g) Altered bowel habits might occur
h) Urinary issues (retention/incontinence/infection (1.3 %-14 %). Urethral meatus stenosis might occur which might need dilatation and possibly surgery
i) Mucorrhoea- Excessive mucus discharge (6.2 %-28.6 %) might occur
j) Prolapse of the sigmoid segment might occur. (1.5 %)
k) Corpus spongiosum protrusion- (6.1 %-15.6 %)
l) Introital or Vaginal stenosis (1.5 %- 22.5 %)
m) Decreased/absent sensations with possible absence of orgasmic capabilities (3.3%)
n) Wound healing issues (5.4 %)
o) Scarring/hypertrophic scar/keloid over abdomen and perineum
p) Colonic Anastomotic leak with possible need for creation of a stoma (ileostomy or colostomy).
q) Abdominal hernia
r) Possible Touch up procedures/surgical corrections (for aesthetic improvement, vaginal stenosis, corpus spongiosum correction etc.
s) Pulmonary embolism—sometimes blood clot in the leg vein can travel up to lungs and cause difficulty in breathing. We use DVT pump and proper IV fluids to prevent. But rarely, deaths have been reported
t) The procedure is irreversible. There will be permanent loss of ability to serve as a male partner in penetrative sexual intercourse.
u) There will be loss of fertility due to removal of testes. This procedure will not grant you the ability to conceive.
v) The procedure in itself does not provide any guarantees to you about successful sexual intercourse or success in marriage or relationship.
w) **Unsatisfactory result**- You may be disappointed with the result of the surgery. It may be necessary to perform additional surgery to improve your results.
x) **Allergic reactions**- In rare cases, local allergies to tape, suture material, or topical preparations have been reported. Systemic reactions which are more serious may

occur to drugs used during surgery and prescription medicines. Allergic reactions may require additional treatment.

y) **Surgical anaesthesia**- Both local and general anaesthesia involve risk. There is the possibility of complications, injury, and even death from all forms of surgical anaesthesia or sedation.

z) **Additional surgery necessary-** There are many variable conditions that may influence the long-term result of male to female genital gender affirmation surgery. Should complications occur, additional surgery or other treatments may be necessary. Besides the cited complications, other complications and risks can occur but are even more uncommon. The practice of medicine and surgery is not an exact science. Although good results are expected, there is no guarantee or warranty expressed or implied, on the results that may be obtained.

9) Discharge instructions- vary individual to individual and will be explained to you at the time of discharge.

10) Post-operative follow-up

Special precautions to be taken at home

a) Diet- liquid to soft diet for 4 weeks.
b) Local cleaning and dressing as explained. Need to wear a clean pad.
c) Have bath regularly.
d) Dilation schedule to be followed as instructed for at least 6 months, and later on if required.
e) Exercise and Sexual activities- usually after 8 weeks
f) Scar care explained.
g) Urinary catheter care if individual is discharged with catheter and need of catheter removal in local area or during follow up
h) Possible need of touch procedures explained

Follow up every month till 6 months, at follow up special focus on dilation.

Follow up with Psychiatrist/psychologist and Endocrinologist as per their advice.

Financial responsibilities

The cost of surgery involves several charges for the services provided. The total includes fees charged by your doctor, the cost of surgical supplies, laboratory tests, blood bank, anaesthesia, and hospital charges, depending on where the surgery is performed. Depending on whether the cost of surgery is covered by an insurance plan, you will be responsible for necessary co-payments, deductibles, and charges not covered.

Additional costs may occur should complications develop from the surgery. Secondary surgery or hospital day-surgery charges involved with reversionary surgery would also be your responsibility.

PART 2- CONSENT FORM

DISCLAIMER

Informed-consent documents are used to communicate information about the proposed surgical treatment of a disease or condition along with disclosure of risks and alternative forms of treatment(s). The informed-consent process attempts to define principles of risk disclosure that should generally meet the needs of most individuals in most circumstances.

However, informed consent documents should not be considered all-inclusive in defining other methods of care and risks encountered. Your plastic surgeon may provide you with additional or different information which is based on all the facts in your particular case and the state of medical knowledge.

Informed-consent documents are not intended to define or serve as the standard of medical care. Standards of medical care are determined on the basis of all of the facts involved in an individual case and are subject to change as scientific knowledge and technology advance and as practice patterns evolve.

CONSENT FOR SURGERY / PROCEDURE or TREATMENT

1) I hereby authorize Dr _____ and such assistants as may be selected to perform the following procedure or treatment**: feminizing genitoplasty with incorporation of sigmoid colon segment for lining the neovaginal cavity.**
2) I consent to the presence of OR staff of either sex to be present in OR during my surgery. I understand that they are present for the safe conduct of my surgery.
3) I recognize that during the course of the operation and medical treatment or anaesthesia, unforeseen conditions may necessitate different procedures than those above. I therefore authorize the above physician and assistants or designees to perform such other procedures that are in the exercise of his or her professional judgment necessary and desirable. The authority granted under this paragraph shall include all conditions that require treatment and are not known to my physician at the time the procedure is begun.
4) I consent to the administration of such anaesthetics considered necessary or advisable. I understand that all forms of anaesthesia involve risk and the possibility of complications, injury, and sometimes death.
5) I understand what my surgeon can and cannot do, and I understand there are no warranties or guarantees, implied or specific about my outcome. I have had the opportunity to explain my goals and understand which desired outcomes are realistic and which are not. All of my questions have been answered, and I understand the inherent (specific) risks of the procedures I seek, as well as those additional risks and complications, benefits, and alternatives. Understanding all of this, I elect to proceed.
6) I consent to be photographed or televised before, during, and after the operation(s) or procedure(s) to be performed, including appropriate portions of my body, for medical, scientific or educational purposes, provided my identity is not revealed by the pictures.

7) For purposes of advancing medical education, I consent to the admittance of observers to the operating room.
8) I consent to the utilization of blood products should they be deemed necessary by my surgeon and/or his/her appointees, and I am aware that there are potential significant risks to my health with their utilization.
9) I understand that the surgeon's fees are separate from the anaesthesia and hospital charges, and the fees are agreeable to me. If a secondary procedure is necessary, further expenditure will be required.
10) I realize that not having the operation is an option. **I understand that no guarantee has been made that the procedure will improve the condition and that the procedure may make my condition worse.**
11) It has been explained to me in a way that I understand**:**
    a. The above treatment or procedure to be undertaken
    b. There may be alternative procedures or methods of treatment
    c. There are risks to the procedure or treatment proposed

I consent to the treatment or procedure. I am satisfied with the explanation.

Name of Individual……Signature of Pt……

Date……

Name of the Witness……

Relationship……

Signature of witness……

Date……

Name of doctor……

Designation……

5) INDIVIDUAL INFORMATION AND CONSENT FOR GENDER AFFIRMING BILATERAL BREAST REDUCTION IN FEMALE TO MALE GENDER INCONGRUENT INDIVIDUALS (The top surgery)

Instructions

This is an informed-consent document that has been prepared to help inform you about female to male gender affirmation chest surgery, its risks, and alternative treatments. It is important that you read this information carefully and completely.

General information

While many gender-incongruent individuals find comfort with their gender identity, role, and expression without surgery, for many others surgery is essential and medically necessary to alleviate their gender incongruence. For the latter group, relief from gender incongruence cannot be achieved without modification of their primary and/or secondary sex characteristics to establish greater congruence with their gender identity and expression.

Gender affirmation is a long process which takes place with counselling and treatment by primary care doctors, mental health professionals, endocrinologists and surgeons. Surgery takes place as a part of this process and must be carefully considered. The best candidates are those who are mature enough to understand the procedure, related complications and have realistic expectations about the results.

Criteria for transmasculine breast reduction surgery

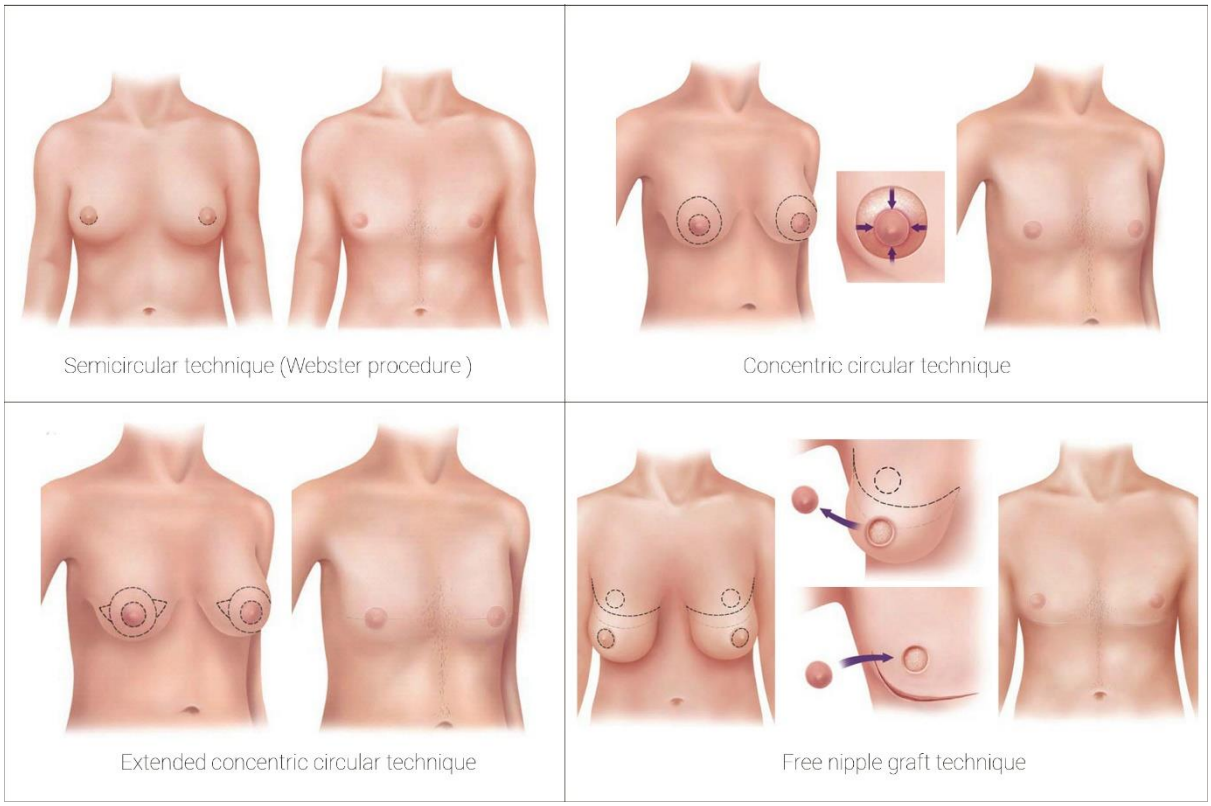
1. Persistent, well-documented gender incongruence.
2. Referral letter for surgery by one mental health professional.
3. Capacity to make a fully informed decision and to give consent for treatment.
4. Age of majority in that country (>18 years in India).
5. If significant medical or mental health concerns are present, they must be reasonably well controlled.

Hormone therapy is not a prerequisite.

There are a variety of different surgical techniques used to reduce and reshape the female chest to have a male appearance, depending on many factors including, but not limited to, the size of the breasts, nipple size and position, sagginess of the breasts, previous use of chest binders or bandages.

These include:

1. Semicircular technique, (Nipple sparing mastectomy/ Webster procedure), commonly known as Key-Hole Surgery. Incision for breast tissue removal is made in the lower half of areolar breast skin junction. As a result, the post- surgical scar is around lower half of nipple areola complex (NAC), at junction of dark and light skin.
2. Concentric circular mastectomy. This is carried out in larger or saggier breasts than above technique. Incision is given in two concentric circles. The inner and outer circle incisions are superficial. The outer circle incision is deep in one area, to facilitate breast tissue removal. The skin between these two incisions is removed in superficial



plane. As a result, the required skin tightening is achieved. This results in circular scar at the periphery of nipple areola complex (NAC).

3. Extended concentric circular mastectomy. This is carried out in larger or saggier breasts than above technique. In addition to the skin between concentric circles, additional triangular areas of skin are removed on either side of NAC. This results in circular scar at periphery of nipple areola complex (NAC) as well as on scars on either side of NAC on both sides of chest.
4. Double incision mastectomy with free nipple areola graft technique. This technique is carried out in very large or saggy breasts. Long incisions on lower aspects of both breasts help in removal of large amounts of skin and breast tissue. The NAC is removed and reapplied in desired location as full thickness skin graft. This results in long scars on both sides of chest, as well as scars around nipple areola complex (NAC).

Your surgeon will discuss various options and a consensus will be reached as to which technique would be most ideal for you.

Alternative treatment

Gender affirmation surgery is an elective surgical operation. Alternative treatment would consist of not undergoing the surgical procedure or wearing garments/ binders to hide the developed breasts.

Risks of Female to Male Gender Affirming breast reduction Surgery

Note: The listed risks and complications are not all inclusive.

Every surgical procedure involves a certain amount of risk. It is important that you understand the risks involved with surgery. An individual's choice to undergo a surgical procedure is based on the comparison of the risk to potential benefit. Although most individuals do not experience the following complications, you should discuss each of them with your surgeon to make sure you understand the risks, potential complications and consequences of female to male gender affirmation surgery.

Despite the rather low complication rate, about one third of individuals will require an additional procedure to improve aesthetic results.

Bleeding: It is possible, though unusual, to experience a heavier than expected bleeding episode during or after surgery. Should post-operative bleeding occur, it may require emergency treatment to drain the accumulated blood, despite the presence of drains. When a significant amount of blood collects at the surgical site it is called a "hematoma" and will likely need return to operating room be drained. Hematoma can occur at any time following surgery or any form of injury to the breast. It is very important to stay off all blood thinning medications for two weeks before and after surgery. Do not take aspirin or any anti-inflammatory medications before or after surgery, as this may increase the risk of bleeding. Non-prescription "herbs" and dietary supplements can increase the risk of surgical bleeding. Vitamin E, untested supplements, a variety of other prescription and over the counter medications should be avoided. After surgery, the risk of bleeding can be reduced significantly by not straining or exerting yourself for at least four weeks, and by keeping your arms at your sides as much as possible for that period. Small amounts of bleeding can be absorbed by the body but can still impact healing.

Infection- Bacteria live on the skin and within the ducts of the breast. You will be given antibiotics through your I.V. at the time of surgery and will take oral antibiotics following surgery. Although infection is unusual after this type of surgery, it may appear in the immediate post-operative period or at any time following the surgery. Should an infection occur, treatment including antibiotics, or additional surgery may be necessary.

Change in nipple and areola skin - You may experience a change in the sensitivity of the nipples and the skin of your breast. Permanent loss of nipple sensation can occur after chest surgery in one or both nipples. Nipple areola sensation may be lost if nipple areola graft techniques are used for the top surgery (breast reduction surgery in transmen). Pigment changes resulting in unusually light or dark skin colour may also occur. Due to variation in skin graft take, there may be some asymmetry in NAC on either side.

Skin scarring- All surgical incisions produce permanent scarring. This is how human bodies heal the wounds. The quality of these scars is unpredictable. Abnormal, hypertrophic and *keloid* scars may occur within the skin and deeper tissue. In some cases, scars may require surgical revision or other treatments. Some scars are limited to the border of the nipple, but individuals with larger breasts may require scars which extend outside of the nipple area. Such scars are more noticeable. Every effort will be made to minimize scars.

Lax Skin- Especially in procedures in which skin is not removed, such as Webster and sometimes in other procedures, loose skin may remain. The individuals are advised to wear a pressure garment for 6-12 weeks, and then wait for upto a year, to allow this loose skin to shrink. However, at the end of this period, some individuals require revisional surgery with consequent scars and the necessary expense to cover this.

Unsatisfactory result- You may be disappointed with the result of the surgery. It may be necessary to perform additional surgery to improve your results. Sometimes, it may not be possible to give a satisfactory result even with revisional surgery.

Pain- Abnormal scarring in skin and the deeper tissues may produce pain. This is a rare complication.

Firmness- Excessive firmness of the chest can occur after surgery due to internal scarring or fat necrosis. The occurrence of this is not predictable, but it is usually temporary. If an area of fat necrosis or scarring appears, this may require additional surgical treatment.

Delayed healing- Wound disruption or delayed wound healing is possible. Some areas of the breast skin or nipple region may not heal normally and may take a long time to heal. It is even possible to have loss of skin or nipple tissue. This may require frequent dressing changes or further surgery to remove the non-healed tissue. Complete loss of the NAC would necessitate later NAC reconstruction or tattooing. Smokers have a greater risk of skin loss and wound healing complications.

Asymmetry- Some chest asymmetry naturally occurs in most men. Often the muscles of the chest on the side of a individual's dominant upper limb are larger. Differences in nipple shape, size, or symmetry may also occur after surgery. Additional surgery may be necessary to revise asymmetry after chest surgery. Some asymmetries may also be non- correctable.

Breast disease- Breast disease and breast cancer can occur independently of a gender affirmation surgery. It is unlikely that the entire breast tissue will be removed after this surgery, and some tissue (around 6% or more) remains. If you have a family history of breast cancer, then you should undergo regular chest area examination. It is recommended that you seek professional care should a breast lump be detected. Such occurrences are rare and usually occur after the teenage years. Top surgery decreases the risk of breast cancer substantially but does not eliminate it.

Allergic reactions- In rare cases, local allergies to tape, suture material, or topical preparations have been reported. Systemic reactions which are more serious may occur to drugs used during surgery and prescription medicines. Allergic reactions may require additional treatment.

Surgical anaesthesia- Both local and general anaesthesia involve risk. There is the possibility of complications, injury, and even death from all forms of surgical anaesthesia or sedation. You will get an opportunity to discuss these issues with the anaesthesiologist during pre-anaesthesia check-up. A separate consent will be taken by the anaesthesiologist.

Additional surgery necessary- There are many variable conditions that may influence the long-term result of female to male gender affirming breast reduction surgery (Top Surgery). Secondary surgery may be necessary to perform additional skin tightening or repositioning of the nipples. Should complications occur, additional surgery or other treatments may be necessary. Other complications and risks can occur but are even more uncommon. The practice of medicine and surgery is not an exact science. Although good results are expected, there is no guarantee or warranty expressed or implied, on the results that may be obtained.

Reversal of surgery

It is imperative that you carefully consider the decision to have your breasts removed. The surgery is irreversible. Although in case of regret (you regret the decision to undergo the gender affirming breast reduction surgery), it may be possible to reconstruct the breasts by implants, fat grafting or flaps in the future, these are not specialized breast tissue. You will never be able to breast feed a child. Also, these additional procedures may necessitate their own costs and may have their own set of complications.

Financial responsibilities

The cost of surgery involves several charges for the services provided. The total includes all infacilty charges ie fees charged by your doctors, the cost of surgical supplies, laboratory tests, blood bank, anaesthesia, and hospital charges, depending on where the surgery is performed. Depending on whether the cost of surgery is covered by an insurance plan, you will be responsible for necessary co-payments, deductibles, and charges not covered.

Additional costs may occur should complications develop from the surgery. Secondary surgery, investigations or hospital stay, and surgery charges involved with revision surgeries would also be your responsibility.

After the procedure--Follow up with the operating surgical team, Mental health professional and Endocrinologist as per their advice.

DISCLAIMER

Informed-consent documents are used to communicate information about the proposed surgical treatment of a disease or condition along with disclosure of risks and alternative forms of treatment(s). The informed-consent process attempts to define principles of risk disclosure that should generally meet the needs of most individuals in most circumstances.

However, informed consent documents should not be considered all-inclusive in defining other methods of care and risks encountered. Your plastic surgeon may provide you with additional or different information which is based on all the facts in your specific case and the state of current medical knowledge.

Informed-consent documents are not intended to define or serve as the standard of medical care. Standards of medical care are determined based on all of the facts involved in a specific

case and are subject to change as scientific knowledge and technology advances and as surgical practice patterns evolve.

CONSENT FOR SURGERY / PROCEDURE or TREATMENT

a) I hereby authorize Dr _____ and such assistants as may be selected to perform the following procedure or treatment**: Gender Affirming breast reduction surgery (Top Surgery).**
b) I recognize that during the course of the operation, anesthesia and medical treatment, unforeseen conditions may necessitate different procedures than those described above. I therefore authorize the above surgeon and assistants or designees to perform any other procedures that are in the exercise of his or her professional judgment necessary and desirable. The authority granted under this paragraph shall include all conditions that require treatment and are not known to my doctor at the time the procedure is begun.
c) I consent to the administration of such anesthetics considered necessary or advisable. I understand that all forms of anesthesia involve risk and the possibility of complications, injury, and sometimes death.
d) I understand what my surgeon can and cannot do, and I understand there are no warranties or guarantees, implied or specific about my outcome. I have had the opportunity to explain my goals and understand which desired outcomes are realistic and which are not. All my questions have been answered to my satisfaction, and I understand the inherent (specific) risks of the procedures I wish to undergo, as well as those additional risks and complications, benefits, and alternatives. I have had ample opportunity to understand the above through this document as well as consultations with my operating team. Having understood all the aspects of my procedure, I chose to proceed with the surgery.
e) I consent to be photographed or televised before, during, and after the operation(s) or procedure(s) to be performed, including appropriate portions of my body, for medical, scientific or educational purposes, provided my identity is not revealed in these media.
f) For purposes of advancing medical education, I consent to the admittance of observers to the operating room.
g) I consent to the utilization of blood products should these be deemed necessary by my surgical team and their appointees, and I am aware that there are potential significant risks to my health with their utilization.
h) I understand that the surgeon's fees are separate from the anaesthesia and hospital charges, and the charges are agreeable to me. If a secondary or a revisional procedure is necessary, further expenditure will be required.
i) I realize that not having the operation is an option.
j) It has been explained to me in a way that I understand**:**
    a. The above treatment or procedure to be undertaken
    b. There may be alternative procedures or methods of treatment, including not undergoing the procedure.
    c. There may be risks and complications related to the procedure or treatment proposed and I have understood these.

Having understood the above details both in writing as well as verbally in my language of choice by my operating team, I consent to the procedure of Top Surgery (Gender affirming breast reduction surgery for transmen).

Name of Individual……Signature of Pt……

Date……

Name of the Witness……

Relationship……

Signature of witness……

Date……

Name of doctor……

Designation……

Signature……

Date……

6) CONSENT FOR BREAST AUGMENTATION SURGERY WITH IMPLANT IN MALE TO FEMALE GENDER INCONGRUENT INDIVIDUALS

GENERAL INFORMATION

While many gender-incongruent individuals find comfort with their gender identity, role, and expression without surgery, for many others surgery is essential and medically necessary to alleviate their gender incongruence. For the latter group, relief from gender incongruence cannot be achieved without modification of their primary and/or secondary sex characteristics to establish greater congruence with their gender identity and expression.

Usually feminizing hormonal therapy will stimulate breast growth, but a subset of individuals may not be satisfied with this growth alone and may opt for surgical breast augmentation procedure.

As this operation is completely cosmetic elective, a detailed consultation is essential so that you are educated about the procedure. For some trans women (male to female transitioning individuals), feminizing surgery is a natural step, and important to their sense of self. However, many choose not to have surgery. Transgender individuals relate to their bodies differently and need to make individual choices that best fit their requirements.

This is an informed-consent document that has been prepared to educate and inform you regarding augmentation mammaplasty surgery with silicone gel-filled implants, its risks, as well as alternative treatment(s).
It is important that you read this information carefully and completely.

Preconditions and requirements prior to transfeminine augmentation mammaplasty

1) Persistent, well-documented gender incongruence.
2) Referral letter for surgery from one mental health professional
3) Capacity to make a fully informed decision and to give consent for treatment.
4) Age of majority (18years or more in India)
5) If significant medical or mental health concerns are present, these must be reasonably well controlled.
6) Recommended (not obligate) criterion- 12 months of feminizing hormone therapy prior to this procedure. This results in realistically the maximum breast growth that can occur by non- surgical means, allowing you to take a better decision whether or not to opt for further surgical breast augmentation.

Information regarding breast implants and the procedure
Breast enlargement is accomplished by inserting a breast implant either behind the breast tissue, or partially or completely under the chest muscles. Incisions are made to keep scars as inconspicuous as possible. Individuals undergoing breast augmentation surgery must consider the following:
Breast augmentation may not be a one-time surgery. Breast implants of any type are not considered lifetime devices. They cannot be expected to last forever. You will likely require future surgery for implant replacement or removal.
Breast implants are manufactured in a variety of shapes, sizes, and with either smooth or textured surfaces. They are made of medical grade silicone rubber and filled with cohesive silicone gel. The method of implant selection and size, along with surgical approach for inserting and positioning breast implants, will depend on your preferences, your specific anatomic features and your surgeon's recommendation.

Your surgeon will make incisions 1) Below the breast (inframammary) or 2) Around the areola (periareolar) or 3) Near the armpit (axillary) locations to insert the implant. Next, your surgeon will place the silicone gel implants either in front of or behind the pectoral muscles. Alternatively, you could have your own body fat graft (multiple stages), muscles or tissue from other parts of your body transplanted into your breasts.

Risks associated with breast augmentation surgery

Note: The listed risks and complications are not all inclusive.

Every surgical procedure has some degree of unavoidable risk. Problems associated with breast implants can be inherent to this type of implanted medical device or relate to complications of a surgical procedure. It is important that you understand these risks and the possible complications associated with them.

The most common risks associated with Breast Augmentation surgery are as follows:

Bleeding: Very little blood is lost at the time of surgery. It is possible, though unusual, to experience a bleeding episode during or after surgery. Should post-operative bleeding occur, it may require emergency treatment to drain the accumulated blood. When a significant amount of blood collects at the surgical site it is called a "hematoma" and will likely need return to operating room be drained. Hematoma can occur at any time following surgery or any form of injury to the breast, and may contribute to capsular contracture, infection, or other problems. It is very important to stay off all blood thinning medications for two weeks before and after surgery. Do not take aspirin or any anti-inflammatory medications before or after surgery, as this may increase the risk of bleeding. Non-prescription "herbs" and dietary supplements can increase the risk of surgical bleeding. Vitamin E, untested supplements, a variety of other prescription and over the counter medications should be avoided. After surgery, the risk of bleeding can be reduced significantly by not straining or exerting yourself for at least four weeks, and by keeping your arms at your sides as much as possible for that period. Small amounts of bleeding can be absorbed by the body but can still impact healing.

Infection: Bacteria live on the skin and within the ducts of the breast. You will be given antibiotics through your intravenous line at the time of surgery and will require to take oral antibiotics following surgery. Although infection is unusual after this type of surgery, it may appear in the immediate post-operative period or at any time following the insertion of a breast implant. Should an infection occur, treatment including antibiotics, possible removal of the implant, or additional surgery may be necessary. The biggest problem in trying to treat an infection is that the body cannot re-sterilize the implant if an infection is present. The implant must be removed. Replacement of the implant should not occur ideally before three months from the time of explanation.

Seroma: Fluid may accumulate around the implant following surgery, trauma, or vigorous exercise. Additional treatment may be necessary to drain fluid accumulation around breast implants. This may contribute to infection, capsular contracture, or other problems.

Asymmetry: It is unusual to find a person with perfectly symmetric breasts. Because the body is not completely symmetric and most people have a dominant upper extremity, there is usually a small amount of asymmetry following this type of surgery. Differences in terms of breast and nipple shape, size, or symmetry may also occur after surgery. These small degrees of asymmetry need to be accepted. Large degrees of asymmetry may be improved with additional surgery.

Capsular Contracture: Your body knows that a large piece of foreign material, such as an implant, does not belong there. As a part of healing process, everyone will develop a layer of scar tissue, which is called a "capsule," internally around the implant. This capsule may tighten

immediately or over time, causing hardening of the breast, distortion, and even pain. A very mild contracture (where one breast is slightly firmer than the other) is common. As this does not cause pain or significant degree of breast distortion, it can be treated with massage. More severe contractures require a surgical procedure to remove the scar tissue from around the implant with removal and/or replacement of the implants. Your operating team will advise you to massage your breasts to move the implants within their cavities, which will help reducing the chances of capsular contracture.

Calcification: Calcium deposits can form in the scar tissue surrounding the implant and may cause pain, firmness, and be visible on mammography. These deposits must be identified as different from calcium deposits that are a sign of breast cancer. Should this occur, additional surgery may be necessary to remove and examine calcifications.

Pain: Expect some pain and discomfort for around one month. This will improve gradually. Severe pain is not expected, and you should present yourself for examination if there is a problem. Implants that are too large for your frame, nerve entrapment, and severe capsular contractures can result in chronic pain.

Change in Nipple and Skin Sensation: Nerves that provide sensation to the nipple come from branches through the ribs and around the side of the breast. When a pocket for the implant is created, these nerves are stretched, and sometimes even cut. Most people will experience a decrease in nipple sensation following this type of surgery, although some become hypersensitive. Approximately 15% will lose sensation and it may take a year before maximal return is seen. In some cases, nipple numbness can be permanent.

Risk of cancer: Though extremely rare, breast implant associated- anaplastic large cell lymphoma, (BIA-ALCL) is a lymphoma associated with textured implants. To reduce the risk of development of this disease, surgeons all over the world have switched from textured to smooth or nanotextured breast implants. BIA-ALCL can also occur in transwomen. Thus, all individuals, including transwomen, should be monitored for development of this disease.
Studies also show an increased risk of breast cancer in trans women compared with cisgender men, probably due to the feminizing hormone therapy. Therefore, transwomen undergoing breast implants should do undergo regular follow-up for monitoring as advised by the physician, including MRI and mammograms. The absolute overall risk of breast cancer in transgender people remains low and therefore it seems sufficient for transgender people using hormone treatment to follow screening guidelines as for cisgender people.

Problems with Healing: Wound disruption or delayed wound healing is possible. Some areas of the breast skin or nipple region may not heal normally and may take a long time to heal. There could be problems with healing due to infection, seroma (fluid collection), or tissue breakdown (necrosis) at the surgical site. Lack of adequate tissue coverage or infection may result in exposure and extrusion of the implant through the skin. Risk factors for tissue breakdown or necrosis include a depressed immune system, steroid use, smoking, history of radiation, and exposure to extreme temperatures. If tissue around the implant does not heal and the implant becomes exposed to the outside world, it will need to be removed. In some cases, incision sites fail to heal normally. Permanent scar deformity may occur. Smokers have a greater risk of skin loss and wound healing complications.

S**utures:** Most surgical techniques use deep sutures. You may notice these sutures after your surgery. Sutures may spontaneously poke through the skin, become visible or produce irritation that requires suture removal.

Poor Appearing Scars: All surgery leaves permanent scars. In some cases, these are more visible than others. Although a normal wound healing is expected after a surgical procedure, sometimes abnormal scars/keloid may occur within the skin and deeper tissues. Scars may be unattractive, raised, or depressed, and of different color than the surrounding skin tone. Scar appearance may also vary within the same scar. Scars may be asymmetrical (appear different on the right and left side of the body). There are many things that you will be required to do and be advised after surgery to improve the appearance of the scars. These may include application of various creams, gels, gel sheets, pressure garments and intra scar injections. It may take up to a year for the final/ long term appearance of scars to emerge. Surgery for scar revision may rarely be required.

Palpable Implants or Visible Skin Wrinkles/Ripples: Visible and palpable wrinkling of implants and breast skin can occur post-operatively. Some wrinkling is normal and expected with breast implants. Lesser the soft tissue covers over the implant (i.e. smaller breasts, thinner individuals, and implants placed above the muscle), more palpable the implant will be. Also, the larger the implant, more easily you will be able to feel it.

Implant Rupture or Deflation: Breast implants are exposed to daily forces that can create wear and tear, and at some point, these may actually rupture. Rupture can also occur as a result of an injury, from no apparent cause (silent rupture), or during mammography. It is also possible to damage an implant at the time of surgery. Damaged or ruptured implants cannot be repaired. These require replacement or removal. Silicone implant rupture may not be obvious to the individual or physician. MRI studies may be necessary to evaluate the possibility of implant rupture, yet it may not be 100% accurate in diagnosing implant integrity. Implant companies recommend MRI's at 3 years post-op and every 2 years after that.

Implant Malposition or Displacement and Tissue Stretching: Displacement, rotation, or migration of a breast implant may occur from its initial placement and can be accompanied by discomfort and/or distortion in breast shape (visible rippling of the skin). Implants are in their ideal position when these are evenly centered under the nipple. Unfortunately, most breasts are not symmetric, and sometimes the nipples are low on the breast. The type of bra worn post-operatively can also influence the positioning of the implant (i.e. sports bras and push-up bras can force the implants too close together; no bra, or those with poor support can allow these to drop too low). The ultimate positioning of the implants can end up slightly too high or low, too close together or far apart, and the breasts may still have some degree of ptosis. Heavier implants will also continue to stretch the skin over time, just like naturally large breasts. Additional surgery may be necessary to correct this problem. It may also, not be possible to resolve this problem once it has occurred.

Stretch marks: Individuals on feminizing hormonal therapy have higher propensity for developing stretch marks on the breast skin which might be dark colored. It might settle with time; however complete resolution of the stretch marks is unusual.

Dissatisfaction with Cosmetic Results: The sizes recommended for your surgery are decided according to how much breast tissue you have, the size of your rib cage, laxity of your skin, your body shape, and finally, your target cup size. Implants that are either too large or too small based on the overall picture can result in a poor cosmetic result. In order to achieve the most natural breast shape and good long-term result, the final implant choice may end up being either larger or smaller than your personal ideal.

Deformity if the Implant is Removed: Over time, you may want to have your implants removed. The implants cause pressure in the chest wall and breast tissue over time, and there may be some atrophy resulting in smaller or droopier breasts once the implants are removed. Some individuals look much better after their implants are removed.

Risks of Surgery and Anesthesia: There are additional risks associated with having surgery, including medication reactions, and complications from anesthesia. Both local and general anesthesia involve risk. There is the possibility of complications, injury, and even death from all forms of surgical anesthesia or sedation. Other risks include pneumonia, deep venous thrombosis (blood clot in the leg), and pulmonary embolus (clot that travels to the lung), and allergic reactions. In rare cases, local allergies to tape, suture material and glues, blood products, topical preparations or injected agents have been reported. Serious systemic reactions including anaphylaxis may occur in response to drugs used during surgery and prescription medicines. These are rare but are possible with any type of surgery.

Cardiac and Pulmonary Complications: Pulmonary complications may occur secondary to both blood clots (pulmonary emboli), fat deposits (fat emboli) or partial collapse of the lungs after general anesthesia. Pulmonary emboli can be life-threatening or fatal in some circumstances. Cardiac complications are a risk with any surgery and anesthesia, even in individuals without symptoms. Should any of these complications occur, you may require hospitalization and additional treatment. If you experience shortness of breath, chest pains, or unusual heart beats after surgery, seek medical attention immediately.

Photographs: Pre-operative and post-operative photos will be taken to help with surgical planning and to document results. Your photos (which never include your face) may also be used for teaching purposes to help doctors or other individuals.

Long-Term Results: Subsequent alterations in breast shape may occur as the result of aging, weight loss, weight gain, or other circumstances not related to your augmentation mammaplasty. Breast sagginess after augmentation may normally occur.

INDIVIDUAL COMPLIANCE

Preoperatively, feminizing hormone therapy should be withheld for a period as advised by the endocrinologist/ physician.

Post operatively, follow all physician instructions carefully; this is essential for the success of your outcome. It is important that the surgical incisions are not subjected to excessive force, swelling, abrasion, or motion during the time of healing. Personal and vocational activity needs to be restricted. Protective dressings and drains should not be removed unless instructed by your plastic surgeon.

Successful post-operative function depends on both surgery and subsequent care. Physical activity that increases your pulse or heart rate may cause bruising, swelling, fluid accumulation and the need for return to surgery. It is wise to refrain from intimate physical activities after surgery until your physician states it is safe. It is important that you participate in follow-up care such as breast massage and movement of implant in pocket, wearing supportive bra topical applications, dressings etc. You should return for aftercare as advised and promote your recovery actively after surgery.

FINANCIAL RESPONSIBILITIES

The cost of surgery involves several charges for the services provided. The total includes infacility charges, fees charged by your surgeon, the cost of surgical supplies, anaesthesia, laboratory tests, and miscellaneous hospital charges, depending on where the surgery is performed. You will be provided an approximate written estimate of charges before surgery. Depending on whether the cost of surgery is covered by an insurance plan, you will be responsible for necessary co-payments, deductibles, and charges not covered.

The fees charged for this procedure do not include-

1) Charges after the discharge such as consults and dressings.
2) Charges for medicines, gels, ointments, gel-sheets, pressure garments, supporting bra etc.
3) Any potential future costs for additional procedures that you elect to have or require to revise, optimize, or complete your outcome.
4) Additional costs may occur should complications develop from the surgery. Secondary /additional surgeries, investigations or hospital stay, and surgery charges involved with revision surgeries would also be your responsibility.
5) The costs for physiotherapy or any supportive therapy if required.

CONSENT FOR SURGERY / PROCEDURE or TREATMENT

a) I hereby authorize Dr _____ and such assistants as may be selected to perform the following procedure or treatment**: AUGMENTATION MAMMAPLASTY WITH IMPLANT.**
b) I recognize that during the surgical procedure and medical treatment or anaesthesia, unforeseen conditions may necessitate different procedures than those specified above. I therefore authorize the above physician and assistants or designees to perform such other procedures that are in the exercise of his or her professional judgment necessary and desirable. The authority granted under this paragraph shall include all conditions that require treatment and are not known to my physician at the time the procedure is begun.
c) I consent to the administration of such anaesthetics considered necessary or advisable. I understand that all forms of anaesthesia involve risk and the possibility of complications, injury, and sometimes death.
d) I understand what my surgeon can and cannot do, and I understand there are no warranties or guarantees, implied or specific about my outcome. I have had the opportunity to explain my goals and understand which desired outcomes are realistic and which are not. All my questions have been answered, and I understand the

inherent (specific) risks of the procedures I seek, as well as those additional risks and complications, benefits, and alternatives. Understanding all of this, I elect to proceed.

e) I consent to be photographed or televised before, during, and after the operation(s) or procedure(s) to be performed, including appropriate portions of my body, for medical, scientific or educational purposes, provided my identity is not revealed by the pictures.
f) For purposes of advancing medical education, I consent to the admittance of observers to the operating room.
g) I consent to the utilization of blood products should these be deemed necessary by my surgeon and/or his/her appointees, and I am aware that there are potential significant risks to my health with their utilization.
h) I understand that the surgeon's fees are separate from the anaesthesia and hospital charges, and the fees are agreeable to me. If a secondary procedure is necessary, further expenditure will be required.
i) I realize that not having the operation is an option.
j) The procedure has been explained to me in a way that I understand**:**
    a. The above treatment or procedure to be undertaken
    b. There may be alternative procedures or methods of treatment
    c. There are risks to the procedure or treatment proposed

I consent to the treatment or procedure and the above listed items (1-10). I have fully discussed all aspects of the procedure, possible complication, aftercare, need for additional/ secondary/ revisional procedures and expenses to my satisfaction.

Name of Individual……Signature of Pt……

Date……

Name of the Witness……

Relationship……

Signature of witness……

Date……

Name of doctor……

Designation…….. Signature……. Date……..

7) INDIVIDUAL INFORMATION AND INFORMED CONSENT FOR PEDICLED ANTEROLATERAL THIGH FLAP PHALLOPLASTY

While many gender-incongruent individuals find comfort with their gender identity, role, and expression without surgery, for many others surgery is essential and medically necessary to alleviate their gender incongruence. For the latter group, relief from gender incongruence cannot be achieved without modification of their primary and/or secondary sex characteristics to establish greater congruence with their gender identity and expression. Phalloplasty (penile reconstruction) inclusive of urethral lengthening and scrotoplasty is of major importance for the psychological and sexual well-being and quality of life in

transgender men. Pedicled Anterolateral thigh flap phalloplasty (pALTp) is a procedure which avoids a donor scar in forearm, often considered a giveaway for free Radial artery forearm flap phalloplasty (fRAFFp) in the transgender community. This is the most common indication for pALTp. The donor area for flap is either thigh. As thigh tissue contains thicker fat layer compared to forearm, often the neophallus is bulkier compared to fRAFFp. On the contrary, greater phallic length can be achieved if desired. Flap sensation is inferior to fRAFFp as only one sensory nerve is available for anastomosis. Also, due to increased bulk, tube in tube urethral reconstruction is often not possible in pALTp, with need for prelamination of urethra in thigh with the help of skin graft/ vaginal mucosa graft or buccal mucosa graft. An erectile implant or stiffener is required around 6 months after the procedure, once the sensation is regained, to enable the individual to engage in sexual intercourse.

This is an informed-consent document that has been prepared to help inform you about female to male sex reassignment genital surgery, its risks, and alternative treatments. This document consists of two parts- the first part is detailed information regarding the procedure and the next is procedure specific consent. Please go through the entire document before consenting to the procedure.

Part 1- Individual information

Introduction

1) **Preconditions for surgery:**
   a) Firm diagnosis of Gender Incongruence, as per ICD-11/ DSM5 by two different mental health professionals.
   b) The reference letters from mental health professionals should include the parameters as mentioned in 7th SOCs, mainly the diagnosis, individual's mental competence to give consent for surgery and hormone therapy and the fact that all co-existing mental health conditions are currently well controlled.
   c) The individual has completed 12 months of hormone therapy under guidance from a hormone specialist/ gender team unless individual is unwilling to take hormones/ unable to take hormones or the hormone therapy is medically contraindicated. (Many individuals in India, especially MTF, are however well adapted in their desired gender role and are unwilling to take hormone therapy).
   d) The individual has experienced living in desired gender role for a period of 12 months.
   e) A legally notarized waiver of liability affidavit on stamp paper, waiving the gender team's liability for removing individual's healthy organs, permanent loss of current sexual functioning and reproductive ability.

2) **Preoperative Requirements:**
   a) Stopping health supplements such as omega, fish oils, herbal products, garlic, green tea etc from 2 weeks prior to surgery.
   b) Stop smoking from 4 weeks prior to surgery.
   c) Limit/ stop alcohol intake 4 weeks prior to surgery. Hormone therapy should be adjusted as per advice of treating endocrinologist.

d) Stop blood thinners if feasible, from 5 days prior to surgery with permission from individual's physician/ cardiologist.

3) <u>Pre-operative Investigations:</u>

a) Complete blood counts, coagulation profile, Blood sugar fasting and PP, LFT, RFT, TSH, viral markers for hepatitis B, C and HIV, EKG, Chest x ray. Other specific investigations if required for co-existing conditions.

b) Colour Doppler (Duplex scan) is usually not required if Allen's test confirms the hand perfusion with either radial or ulnar artery.

4) **<u>Options for the proposed surgical procedure and details</u>**

Other surgical options/alternatives like metaidoioplasty, RAFFp, musculocutaneous latissimus dorsi flap, fibula flap, deltoid flap, lateral arm flap and combined flap phalloplasties etc. are used less often. The pros and cons of these options have been explained to me. I understand that in view of inferior sensation compared to RAFFp, and often the inability to form a tube in tube urethra in ALTp with necessity of additional procedures and increased chances of urinary complications, individuals often opt for RAFFp rather than this procedure.

5) <u>Procedure specific information:</u>

The procedure as described below may be varied and all steps may not be carried out. If needed, extra steps may be carried out and the procedure may be varied from the below description if operative situation so demands or as per surgeon's discretion.

a) General individual identifiers, names of admitting surgeons, individual's and witness's signatures, permission for photo and videography etc are usually part of general hospital consent and, also may be a part of this consent. Higher risk due to some co-existing condition and anaesthesia consents are separate.

b) The perforator vessels of flap are auscultated, and flap marking is done in the designated thigh.

c) Shaving of genital area, thighs and forearm will be carried out just prior to the surgery. A urinary catheter will be inserted. The surgery is generally done sequentially on perineum and then on thigh. In lithotomy position, the surgical team first removes the vaginal lining and closes the vagina, lengthens the urethra, reconstructs the scrotum and transposes the clitoris to pubic area. A drain is often left in the obliterated vaginal cavity. Many a times, this procedure has already been done earlier at the time of hysterectomy and salpingo-oophorectomy.

d) After this in supine position, the thigh is dissected, and previously marked ALT flap is raised (with prelaminated urethra/ tube in tube urethra/ no urethra). The flap is tubed to form a neophallus and shifted to pubic area, where it's base is inset over the transposed clitoris. If a phallic urethra is present, it may or may not be anastomosed to previously or just extended fixed part of urethra at this time. If the urethral anastomosis is done, a diverting cystostomy may or may not be done.

e) The lateral cutaneous nerve of forearm present in flap is anastomosed to one of the recipient nerves.
f) Skin graft harvested from the other thigh is applied to the ALT donor thigh, and secured with staples, sutures, dressing and slab.
g) All wounds are now closed leaving behind drains as required. Dressings are done in a manner permitting ready examination of neophallus for monitoring of circulation.

6) **Postoperative Course:** After ALT phalloplasty 4-5 days stay may be required in ward/ room. During the period of stay my vital signs will be monitored and initially, neophallus circulation will be monitored frequently by various methods. I may be put on blood thinners which may increase my risk of bleeding and necessity of blood transfusion. My epidural anaesthesia may be continued for 3-4 days for facilitating analgesia and lowering the dose of analgesics. Thrombo-embolic deterrent stockings will on for a period of 4-5 days. Even so, I will be required to carry out regular ankle movements. I will be expected to avoid movements at that hip, which is the donor site of flap. I will be mobilized and expected to start walking on day 4/5, with expected discharge from hospital. I will be expected to carry out instructions and take medicines regularly and will come for follow-up as advised. I will be expected to stay in town for around one month from the day of admission. My urinary catheter will be removed at around 2-3 weeks depending on healing and recovery. If a cystostomy has been done, it may be removed at 3-6 weeks from day of surgery. Sensations are typically gained in neophallus at around 6 months, at which time an erectile implant/ stiffener may be inserted in neophallus, together with silicone testicles in neoscrotum.

7) **Complications** –

Note: The listed risks and complications are not all inclusive.

While majority of individuals have an uneventful surgery and recovery, few cases may be associated with complications. These are seen infrequently and not all the ones listed below are applicable to one individual. However, it is important that you are aware of the complications/risks that may arise out of this procedure which are as below:

a) Bleeding- It is possible, though unusual, to experience a bleeding episode during or after surgery and may require blood transfusion. Should post-operative bleeding occur, it may require emergency treatment to stop bleeding, drain accumulated blood or give a blood transfusion. You should reveal all the medications that you have been taking to the surgeon so that medicines that can cause bleeding can be stopped or its dose adjusted before the surgery.
b) Infection- Bacteria live on the skin and near the perineal area. You will be given antibiotics through your I.V. at the time of surgery and postoperative period and will be required to take oral antibiotics on discharge. Although infection is unusual after this type of surgery, it may appear in the immediate post-operative period or at any time following the surgery. Should an infection occur, treatment including antibiotics, or additional surgery may be necessary.
c) Skin graft related complications- The skin graft applied over the thigh might not survive completely, which can necessitate prolonged dressings or sometimes repeat

grafting. As the skin graft is thin compared to normal skin, it graft might break down post operatively or can result in unstable scars which might require additional procedures. The skin graft can also have a different colour and texture compared to surrounding normal skin.

d) **Neophallus related complications-** During surgery, an abnormal course of perforators can lead to abandonment of the procedure (very rare).
e) After transfer of the flap to the groin, vascular (venous or arterial) thrombosis might occur at leading to flap congestion or failure- which requires immediate exploration and correction. Vascular (venous or arterial) thrombosis or compression may also present at any time after the procedure (with decreasing chances as time passes) leading to flap failure and loss of neophallus in spite of salvage procedures. Rarely, total loss of neophallus might occur, which may require later reconstruction using other surgical options.
f) **Urinary complications-** Urinary fistulas (leakage of urine) or stenosis (partial or complete blockage of urine flow) can occur in the extended urethral segments immediately or some ime after surgery. Incidence of such complications can be up to 40%. These may require further investigations and surgery to correct or to divert the urine. Sometimes the urinary complications may not be correctable or may recur. In these instances, a permanent urinary passage may be created along the course of urethra.
g) **Sensory deficit of neophallus**- Usually protective sensations return at around 6 months after surgery. Impairment of sensations or total lack of sensations might occur, though uncommon.
h) **Donor thigh complications)-** You might develop swelling (oedema) and stiffness, nerve or vascular injury, altered/loss of sensations and movements, numbness, burning/shooting pain, hypertrophic scarring, contracture.
i) **Skin scarring**- All surgical incisions and donor sites (forearm and thighs) produce permanent scarring. The quality of these scars is unpredictable. Abnormal and hypertrophic scars may occur within the skin and deeper tissue. In some cases, scars may require surgical revision or other treatments. Every effort will be made to minimize scars.
j) **Unsatisfactory result**- You may be disappointed with the result of the surgery. It may be necessary to perform additional surgery to improve your results.
k) **Delayed healing and prolonged hospital stay**- Wound disruption or delayed wound healing is possible and may result in prolonged hospital stay. Partial flap loss or skin graft loss might take a long time to heal. This may require frequent dressing changes or further surgery to remove the non-healed tissue. Smokers have a greater risk of skin loss and wound healing complications.
l) **Allergic reactions**- In rare cases, local allergies to tape, suture material, or topical preparations have been reported. Systemic reactions which are more serious may occur to drugs used during surgery and prescription medicines. Allergic reactions may require additional treatment.
m) **Anaesthesia related risks**- Both local and general anaesthesia involve risk. There is the possibility of complications, injury, and even death from all forms of surgical anaesthesia or sedation.
n) **Additional surgery necessary-** There are many variable conditions that may influence the long-term result of female to male genital gender affirmation surgery. Should

complications occur, additional surgery or other treatments may be necessary. Complications and risks other than the cited ones can occur but are even more uncommon. The practice of medicine and surgery is not an exact science. Although good results are expected, there is no guarantee or warranty expressed or implied, on the results that may be obtained.

o) Vaginal closure together with phalloplasty will affect on a permanent bases, your current sexual functioning. You have been given no guarantees about successful sexual intercourse or success in marriage and relationships.

8) **Post-operative follow-up---** Discharge instructions- vary individual to individual.

a) Local cleaning and dressing (if required) as explained.
b) Sutureline and scar care and regular physiotherapy.
c) Urinary catheter care if individual is discharged with catheter and need of catheter removal in local area or during follow up.
d) Possible need of touch up procedures/further procedures explained
e) Need to reduce activities & take time off from work six to eight weeks or longer.

f) Need for a support person in the post-operative period to assist with daily activities such as self-care & grooming, meal preparation, laundry, etc.

g) Need for regular follow-up with care providers for 3-4 weeks as per given schedule during initial post-operative period and less frequently later.

h) Follow up with mental health professional and hormone prescribing physician as per their advice.

Financial responsibilities

The cost of surgery involves several charges for the services provided. The total includes fees charged by your doctor, the cost of surgical supplies, laboratory tests, blood bank, anaesthesia, and hospital charges, depending on where the surgery is performed. Depending on whether the cost of surgery is covered by an insurance plan, you will be responsible for necessary co-payments, deductibles, and charges not covered.

Additional costs may occur should complications develop from the surgery. Secondary /additional surgeries, investigations or hospital stay and surgery charges involved with revision surgeries would also be your responsibility.

PART 2- CONSENT FORM

DISCLAIMER

Informed-consent documents are used to communicate information about the proposed surgical treatment of a disease or condition along with disclosure of risks and alternative forms of treatment(s). The informed-consent process attempts to define principles of risk disclosure that should generally meet the needs of most individuals in most circumstances.

However, informed consent documents should not be considered all-inclusive in defining other methods of care and risks encountered. Your plastic surgeon may provide you with additional or different information which is based on all the facts in your particular case and the state of medical knowledge.

Informed-consent documents are not intended to define or serve as the standard of medical care. Standards of medical care are determined on the basis of all of the facts involved in an individual case and are subject to change as scientific knowledge and technology advance and as practice patterns evolve.

CONSENT FOR SURGERY / PROCEDURE or TREATMENT

a) I hereby authorize Dr _____ and such assistants as may be selected to perform the following procedure or treatment**: pedicled anterolateral thigh flap phalloplasty.**
b) I consent to the presence of OR staff of either sex to be present in OR during my surgery. I understand that they are present for the safe conduct of my surgery.
c) I recognize that during the course of the operation and medical treatment or anesthesia, unforeseen conditions may necessitate different procedures than those above. I therefore authorize the above physician and assistants or designees to perform such other procedures that are in the exercise of his or her professional judgment necessary and desirable. The authority granted under this paragraph shall include all conditions that require treatment and are not known to my physician at the time the procedure is begun.
d) I consent to the administration of such anesthetics considered necessary or advisable. I understand that all forms of anesthesia involve risk and the possibility of complications, injury, and sometimes death.
e) I understand what my surgeon can and cannot do, and I understand there are no warranties or guarantees, implied or specific about my outcome. I have had the opportunity to explain my goals and understand which desired outcomes are realistic and which are not. All of my questions have been answered, and I understand the inherent (specific) risks of the procedures I seek, as well as those additional risks and complications, benefits, and alternatives. Understanding all of this, I elect to proceed.
f) I consent to be photographed or televised before, during, and after the operation(s) or procedure(s) to be performed, including appropriate portions of my body, for medical, scientific or educational purposes, provided my identity is not revealed by the pictures.
g) For purposes of advancing medical education, I consent to the admittance of observers to the operating room.
h) I consent to the utilization of blood products should they be deemed necessary by my surgeon and/or his/her appointees, and I am aware that there are potential significant risks to my health with their utilization.
i) I understand that the surgeon's fees are separate from the anaesthesia and hospital charges, and the fees are agreeable to me. If a secondary procedure is necessary, further expenditure will be required.
j) I realize that not having the operation is an option.
k) It has been explained to me in a way that i understand**:**
    a. The above treatment or procedure to be undertaken

b. There may be alternative procedures or methods of treatment
c. There are risks to the procedure or treatment proposed

I consent to the treatment or procedure. I am satisfied with the explanation.

Name of Individual……Signature of Pt……

Date……

Name of the Witness……

Relationship……

Signature of witness……

Date……

Name of doctor……

Designation……

Signature…… Date……

8) INDIVIDUAL INFORMATION AND INFORMED CONSENT FOR FREE RADIAL ARTERY FOREARM FLAP PHALLOPLASTY

While many gender-incongruent individuals find comfort with their gender identity, role, and expression without surgery, for many others surgery is essential and medically necessary to alleviate their gender incongruence. For the latter group, relief from gender incongruence cannot be achieved without modification of their primary and/or secondary sex characteristics to establish greater congruence with their gender identity and expression. Phalloplasty (penile reconstruction) inclusive of urethral lengthening and scrotoplasty is of major importance for the psychological and sexual well-being and quality of life in transgender men. Free Radial artery forearm flap phalloplasty (fRAFFp) is considered he gold standard technique, against which all techniques are compared. Currently, the majority of phalloplasties world over are being done with this technique. This technique results in a near normal size and shape of penis, mimicking a circumcised erect penis. As there is currently no reconstructive technique which can provide a natural physiologic erection, the penis is reconstructed in erect size and a stiffener or erectile implant is inserted later to enable the individual to engage in penetrative sexual intercourse. In some cases, a segment of radius bone may be taken as stiffener at the time of flap elevation, thus avoiding the need of later surgery. This technique is known as osteocutaneous fRAFFp (ofRAFFp). fRAFFp also provides good sensations (touch and erogenous) as two nerves are available for anastomosis. The urethra in fRAFFp is formed with tube in tube technique from the hairless ulnar aspect of forearm.

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Part 1- Individual information

Introduction

The radial forearm free flap has become the most frequently used surgical technique for phalloplasty, because it meets the goals of creating a sensate neophallus with functioning urethra and allows penetrative intercourse. It can be a single stage or more commonly multi-staged procedure

1) Preconditions for surgery:

a) Firm diagnosis of Gender Incongruence, as per ICD-11/ DSM5 by two different mental health professionals.
b) The reference letters from mental health professionals should include the parameters as mentioned in 7th SOCs, mainly the diagnosis, individual's mental competence to give consent for surgery and hormone therapy and the fact that all co-existing mental health conditions are currently well controlled.
c) The individual has completed 12 months of hormone therapy under guidance from a hormone specialist/ gender team unless individual is unwilling to take hormones/ unable to take hormones or the hormone therapy is medically contraindicated. (Many individuals in India, especially MTF, are however well adapted in their desired gender role and are unwilling to take hormone therapy).
d) The individual has experienced living in desired gender role for a period of 12 months.
e) A legally notarized waiver of liability affidavit on stamp paper, waiving the gender team's liability for removing individual's healthy organs, permanent loss of current sexual functioning and reproductive ability.

2) Preoperative Requirements:

a) Stopping health supplements such as omega, fish oils, herbal products, garlic, green tea etc from 2 weeks prior to surgery.
b) Stop smoking from 4 weeks prior to surgery.
c) Limit/ stop alcohol intake 4 weeks prior to surgery. Hormone therapy should be adjusted as per advice of treating endocrinologist.
d) Stop blood thinners if feasible, from 5 days prior to surgery with permission from individual's physician/ cardiologist.

3) Pre-operative Investigations:

a) Complete blood counts, coagulation profile, Blood sugar fasting and PP, LFT, RFT, TSH, viral markers for hepatitis B, C and HIV, EKG, Chest x ray. Other specific investigations if required for co-existing conditions.

b) Colour Doppler (Duplex scan) is usually not required if Allen's test confirms the hand perfusion with either radial or ulnar artery.

4) <u>Options for the proposed surgical procedure and details</u>

Other surgical options/alternatives like metaidoioplasty, anterolateral thigh flap, musculocutaneous latissimus dorsi flap, fibula flap, deltoid flap, lateral arm flap and combined flap phalloplasties etc. are used less often. The pros and cons of these options have been explained to me. I understand that there will be a visible scar/ grafted area in the donor forearm after RAFFp, which is often the reason why many individuals do not opt for this procedure.

5) <u>Procedure specific information:</u>

The procedure as described below may be varied and all steps may not be carried out. If needed, extra steps may be carried out and the procedure may be varied from the below description if operative situation so demands or as per surgeon's discretion.

a) General individual identifiers, names of admitting surgeons, individual's and witness's signatures, permission for photo and videography etc are usually part of general hospital consent and also may be a part of this consent. Higher risk due to some co-existing condition and anaesthesia consents are separate.
b) Shaving of genital area, thighs and forearm will be carried out just prior to the surgery. A urinary catheter will be inserted. The surgery is generally done with a two- team approach. While one surgical team works on the donor forearm for raising the flap together with blood vessels and nerves, reconstructing urethra, tubing the flap and sculpting the coronal sulcus and glans, the other surgical team operates on perineum, thighs and pubic area. This second team removes the vaginal lining and closes the vagina, lengthens the urethra, reconstructs the scrotum and transposes the clitoris to pubic area. Then, the recipient vessels and nerves are dissected in thigh and prepared for anastomosis. In many cases, the perineal part of procedure has been done earlier, at the time of hysterectomy and salpingo-oophorectomy (HSOV).
c) The reconstructed phallus is now detached from forearm and attached to pubic area. It's blood vessels are joined to recipient structures so that the circulation can restart. The nerves are also joined. Clitoris is usually buried at the base of neophallus. The phallic urethra may be joined to extended fixed part of urethra now or at a later sitting. In case the urethra is joined, a suprapubic cystostomy may be done to divert urine away from the healing urethral anastomosis.
d) Skin graft harvested from thigh is applied to the forearm, and secured with staples, sutures, dressing and slab.
e) All wounds are now closed leaving behind drains as required. Dressings are done in a manner permitting ready examination of neophallus for monitoring of circulation.

6) **<u>Postoperative Course:</u>** As RAFF phalloplasty is a long and complicated procedure with potential for significant blood loss, 1-2 days stay in high dependency unit/ surgical intensive care unit might be needed followed by 5-7 days in ward/ room. During the period of stay my vital signs will be monitored and initially, neophallus circulation will

be monitored frequently by various methods. I may be put on blood thinners which may increase my risk of bleeding and necessity of blood transfusion. My epidural anaesthesia may be continued for 3-4 days for facilitating analgesia and lowering the dose of analgesics. Thrombo-embolic deterrent stockings will on for a period of 4-7 days. Even so, I will be required to carry out regular ankle movements. I will be expected to avoid movements at that hip, which is the site for microvascular anastomosis. I will be mobilized and expected to start walking on day 6/7, with expected discharge from hospital on day 7-10. I will be expected to carry out instructions and take medicines regularly and will come for follow-up as advised. I will be expected to stay in town for around one month from the day of admission. My urinary catheter will be removed at around 2-3 weeks depending on healing and recovery. If a cystostomy has been done, it may be removed at 3-6 weeks from day of surgery. Sensations are typically gained in neophallus at around 6 months, at which time an erectile implant/ stiffener may be inserted in neophallus, together with silicone testicles in neoscrotum.

7) **<u>Complications</u>** –

Note: The listed risks and complications are not all inclusive.

While majority of individuals have an uneventful surgery and recovery, few cases may be associated with complications. These are seen infrequently and not all the ones listed below are applicable to one individual. However, it is important that you are aware of the complications/risks that may arise out of this procedure which are as below:

a) **Bleeding**- It is possible, though unusual, to experience a bleeding episode during or after surgery and may require blood transfusion. Should post-operative bleeding occur, it may require emergency treatment to stop bleeding, drain accumulated blood or give a blood transfusion. You should reveal all the medications that you have been taking to the surgeon so that medicines that can cause bleeding can be stopped or its dose adjusted before the surgery.

b) **Infection**- Bacteria live on the skin and near the perineal area. You will be given antibiotics through your I.V. at the time of surgery and postoperative period and will be required to take oral antibiotics on discharge. Although infection is unusual after this type of surgery, it may appear in the immediate post-operative period or at any time following the surgery. Should an infection occur, treatment including antibiotics, or additional surgery may be necessary.

c) **Vascular compromise (donor forearm)**- Loss of blood supply to donor forearm is a rare complication. It is usually detected and managed intraoperatively with vascular anastomosis, venous graft or in certain cases, abandoning the procedure.

d) **Skin graft related complications**- The skin graft applied over the forearm might not survive completely, which can necessitate prolonged dressings or sometimes repeat grafting. As the skin graft is thin compared to normal skin, it graft might break down post operatively or can result in unstable scars which might require additional procedures. The skin graft can also have a different colour and texture compared to surrounding normal skin.

e) **Neophallus related complications-** During surgery, poor arterial supply or venous outflow of neophallus while still attached to forearm can occur, leading to abandonment of the procedure (very rare).

f) After transfer of the radial forearm flap to the groin, vascular (venous or arterial) thrombosis might occur at the site of anastomosis (leading to flap failure)- which requires immediate exploration and repair. Vascular (venous or arterial) thrombosis may also present at any time after the procedure (with decreasing chances as time passes) leading to flap failure and loss of neophallus in spite of salvage procedures. Rarely, total loss of neophallus might occur, which may require later reconstruction using other surgical options.

g) **Urinary complications-** Urinary fistulas (leakage of urine) or stenosis (partial or complete blockage of urine flow) can occur in the extended urethral segments immediately or sometime after surgery. Incidence of such complications can be up to 40%. These may require further investigations and surgery to correct or to divert the urine. Sometimes the urinary complications may not be correctable or may recur. In these instances, a permanent urinary passage may be created along the course of urethra.

h) **Sensory deficit of neophallus**- Usually protective sensations return at around 6 months after surgery. Impairment of sensations or total lack of sensations might occur, though uncommon.

i) **Donor site (upper limb Complications)-** You might develop swelling (oedema) and stiffness, nerve or vascular injury, altered/loss of sensations and movements, numbness, burning/shooting pain, scarring/keloid, contracture. Tourniquet related complications including ischemia and nerve injury.

j) **Skin scarring**- All surgical incisions and donor sites (forearm and thighs) produce permanent scarring. The quality of these scars is unpredictable. Abnormal and hypertrophic scars may occur within the skin and deeper tissue. In some cases, scars may require surgical revision or other treatments. Every effort will be made to minimize scars.

k) **Unsatisfactory result**- You may be disappointed with the result of the surgery. It may be necessary to perform additional surgery to improve your results.

l) **Delayed healing and prolonged hospital stay**- Wound disruption or delayed wound healing is possible and may result in prolonged hospital stay. Partial flap loss or skin graft loss might take a long time to heal. This may require frequent dressing changes or further surgery to remove the non-healed tissue. Smokers have a greater risk of skin loss and wound healing complications.

m) **Allergic reactions**- In rare cases, local allergies to tape, suture material, or topical preparations have been reported. Systemic reactions which are more serious may occur to drugs used during surgery and prescription medicines. Allergic reactions may require additional treatment.

n) **Anaesthesia related risks**- Both local and general anaesthesia involve risk. There is the possibility of complications, injury, and even death from all forms of surgical anaesthesia or sedation.

o) **Additional surgery necessary-** There are many variable conditions that may influence the long-term result of female to male genital gender affirmation surgery. Should complications occur, additional surgery or other treatments may be necessary. Complications and risks other than the cited ones can occur but are even more

uncommon. The practice of medicine and surgery is not an exact science. Although good results are expected, there is no guarantee or warranty expressed or implied, on the results that may be obtained.

p) Vaginal closure together with phalloplasty will affect on a permanent bases, your current sexual functioning. You have been given no guarantees about successful sexual intercourse or success in marriage and relationships.

8) **Post-operative follow-up---** Discharge instructions- vary individual to individual.

a) Local cleaning and dressing (if required) as explained.
b) Sutureline and scar care and regular physiotherapy.
c) Urinary catheter care if individual is discharged with catheter and need of catheter removal in local area or during follow up.
d) Possible need of touch up procedures/further procedures explained
e) Need to reduce activities & take time off from work six to eight weeks or longer.

f) Need for a support person in the post-operative period to assist with daily activities such as self-care & grooming, meal preparation, laundry, etc.

g) Need for regular follow-up with care providers for 3-4 weeks as per given schedule during initial post-operative period and less frequently later.

h) Follow up with mental health professional and hormone prescribing physician as per their advice.

Financial responsibilities

The cost of surgery involves several charges for the services provided. The total includes fees charged by your doctor, the cost of surgical supplies, laboratory tests, blood bank, anaesthesia, and hospital charges, depending on where the surgery is performed. Depending on whether the cost of surgery is covered by an insurance plan, you will be responsible for necessary co-payments, deductibles, and charges not covered.

Additional costs may occur should complications develop from the surgery. Secondary /additional surgeries, investigations or hospital stay and surgery charges involved with revision surgeries would also be your responsibility.

PART 2- CONSENT FORM

DISCLAIMER

Informed-consent documents are used to communicate information about the proposed surgical treatment of a disease or condition along with disclosure of risks and alternative forms of treatment(s). The informed-consent process attempts to define principles of risk disclosure that should generally meet the needs of most individuals in most circumstances.

However, informed consent documents should not be considered all-inclusive in defining other methods of care and risks encountered. Your plastic surgeon may provide you with additional or different information which is based on all the facts in your particular case and the state of medical knowledge.

Informed-consent documents are not intended to define or serve as the standard of medical care. Standards of medical care are determined on the basis of all of the facts involved in an individual case and are subject to change as scientific knowledge and technology advance and as practice patterns evolve.

CONSENT FOR SURGERY / PROCEDURE or TREATMENT

a) I hereby authorize Dr _____ and such assistants as may be selected to perform the following procedure or treatment**: free radial forearm flap phalloplasty.**
b) I consent to the presence of OR staff of either sex to be present in OR during my surgery. I understand that they are present for the safe conduct of my surgery.
c) I recognize that during the course of the operation and medical treatment or anesthesia, unforeseen conditions may necessitate different procedures than those above. I therefore authorize the above physician and assistants or designees to perform such other procedures that are in the exercise of his or her professional judgment necessary and desirable. The authority granted under this paragraph shall include all conditions that require treatment and are not known to my physician at the time the procedure is begun.
d) I consent to the administration of such anesthetics considered necessary or advisable. I understand that all forms of anesthesia involve risk and the possibility of complications, injury, and sometimes death.
e) I understand what my surgeon can and cannot do, and I understand there are no warranties or guarantees, implied or specific about my outcome. I have had the opportunity to explain my goals and understand which desired outcomes are realistic and which are not. All of my questions have been answered, and I understand the inherent (specific) risks of the procedures I seek, as well as those additional risks and complications, benefits, and alternatives. Understanding all of this, I elect to proceed.
f) I consent to be photographed or televised before, during, and after the operation(s) or procedure(s) to be performed, including appropriate portions of my body, for medical, scientific or educational purposes, provided my identity is not revealed by the pictures.
g) For purposes of advancing medical education, I consent to the admittance of observers to the operating room.
h) I consent to the utilization of blood products should they be deemed necessary by my surgeon and/or his/her appointees, and I am aware that there are potential significant risks to my health with their utilization.
i) I understand that the surgeon's fees are separate from the anaesthesia and hospital charges, and the fees are agreeable to me. If a secondary procedure is necessary, further expenditure will be required.
j) I realize that not having the operation is an option.
k) It has been explained to me in a way that i understand**:**
    a. The above treatment or procedure to be undertaken

b. There may be alternative procedures or methods of treatment
c. There are risks to the procedure or treatment proposed

I consent to the treatment or procedure. I am satisfied with the explanation.

Name of Individual……Signature of Pt……

Date……

Name of the Witness……

Relationship……

Signature of witness…… Date……

Name of doctor……Designation……

Signature…… Date……

9) INDIVIDUAL INFORMATION AND INFORMED CONSENT FOR METAIDOIOPLASTY

While many gender-incongruent individuals find comfort with their gender identity, role, and expression without surgery, for many others surgery is essential and medically necessary to alleviate their gender incongruence. For the latter group, relief from gender incongruence cannot be achieved without modification of their primary and/or secondary sex characteristics to establish greater congruence with their gender identity and expression. Phalloplasty (penile reconstruction) is of major importance for the psychological and sexual well-being and quality of life in transgender men. However, phalloplasty is a major surgery with significant morbidity. Also, many a times, it is done in multiple stages. Therefore, many transmen opt not to undergo this procedure and instead opt for metaidoioplasty, which is a relatively minor, single staged procedure, with chances of less urinary complications, and preserving physiologic erection, natural sensation and orgasm. In a significant number of cases, metaidoioplasty will not achieve the phallic length capable of penetrative sexual intercourse with a female partner or micturition in erect position with good stream. It is usually possible to proceed to phalloplasty, if you so desire, later.

This is an informed-consent document that has been prepared to help inform you about female to male sex reassignment genital surgery, its risks, and alternative treatments. This document consists of two parts- the first part is detailed information regarding the procedure and the next is procedure specific consent. Please go through the entire document before consenting to the procedure.

Part 1- Individual information

Introduction

1) **Preconditions for surgery:**
   a) Firm diagnosis of Gender Incongruence, as per ICD-11/ DSM5 by two different mental health professionals.
   b) The reference letters from mental health professionals should include the parameters as mentioned in 7th SOCs, mainly the diagnosis, individual's mental competence to give consent for surgery and hormone therapy and the fact that all co-existing mental health conditions are currently well controlled.
   c) The individual has completed 12 months of hormone therapy under guidance from a hormone specialist/ gender team unless individual is unwilling to take hormones/ unable to take hormones or the hormone therapy is medically contraindicated. (Many individuals in India, especially MTF, are however well adapted in their desired gender role and are unwilling to take hormone therapy).
   d) The individual has experienced living in desired gender role for a period of 12 months.
   e) A legally notarized waiver of liability affidavit on stamp paper, waiving the gender team's liability for removing individual's healthy organs, permanent loss of current sexual functioning and reproductive ability.

2) **Preoperative Requirements:**
   a) Stopping health supplements such as omega, fish oils, herbal products, garlic, green tea etc from 2 weeks prior to surgery.
   b) Stop smoking from 4 weeks prior to surgery.
   c) Limit/ stop alcohol intake 4 weeks prior to surgery. Hormone therapy should be adjusted as per advice of treating physician/ endocrinologist.
   d) Stop blood thinners if feasible, from 5 days prior to surgery with permission from individual's cardiologist.
   e) Depending on the protocol, you may be required to use a suction device and local application of testosterone analogues for 2-4 weeks prior to the procedure.

3) **Pre-operative Investigations:**
   Complete blood counts, coagulation profile, Blood sugar fasting and PP, LFT, RFT, TSH, viral markers for hepatitis B, C and HIV, EKG, Chest x ray, Ultrasound whole abdomen. Other specific investigations if required for co-existing conditions.

4) **Options and alternate procedures:** Phalloplasty by various methods such as radial artery forearm flap, anterolateral thigh flap, musculocutaneous latissimus dorsi flap and others.

5) **Procedure specific information:**
   a) General individual identifiers, names of admitting surgeons, individual's and witness's signatures, permission for photo and videography etc are usually part of

general hospital consent and, also may be a part of this consent. Higher risk due to some co-existing condition and anaesthesia consents are separate.

b) Shaving of genital area and thighs will be carried out just prior to the surgery. A urinary catheter will be inserted.

c) <u>Surgical procedure:</u>

Metaidoioplasty may be done in isolation or can be combined with hysterectomy, salpingo-oophorectomy, vaginectomy, urethroplasty and scrotoplasty (with or without testicular implants) in the same sitting.

In metoidioplasty the natural clitoral chordee is released and the suspensory ligaments are transected to straighten the phallus. Depending upon the type of metaidoioplasty (simple metaidoioplasty/ Ring metaidoioplasty/Belgrade Metaidoioplasty) the surgeon might take mucosa from inside your mouth, or vaginal mucosa when done along with vaginectomy, or skin flap from the labia minora to extend the urethra (reconstruct the fixed part of male urethra) up to the tip or corona of clitoris. The skin closure is then carried out to complete the reconstruction.

Scrotoplasty can also be done in the same sitting to obtain a male-like appearance of the genitalia.

A supra pubic urinary catheter might be placed for around 3 weeks after surgery. Urethral stent might be placed in some cases which may be removed after 10 days. Alternatively, a Foleys catheter might be placed for 3 weeks.

6) **<u>Postoperative Course:</u>** After surgery, you will be having a urinary catheter for around 3 weeks. Hospital stay after surgery is usually for 3-7 days.
Depending on the protocol, you may require the post-operative use of vacuum pump or a syringe suction device, starting 3 weeks after surgery to maximize the result.

7) **<u>Complications</u>** -post operative complications can be minor (that can be managed without surgery) or major (those requiring additional surgery)

Minor complications: The minor complication rate ranges from 17.5% to 35%.

Bleeding- It is possible, though unusual, to experience a bleeding episode during or after surgery. Should post-operative bleeding occur, it may require drainage. You should reveal all the medications that you have been taking to the surgeon so that medicines that can cause bleeding can be stopped or its dose adjusted before the surgery.

Infection- Bacteria live on the skin and near the perineal area. You will be given antibiotics through your I.V. at the time of surgery and post operatively and will be required to take oral antibiotics on discharge. Although infection is unusual after this type of surgery, it may appear in the immediate post-operative period or at any time following the surgery.

Delayed healing- Wound disruption or delayed wound healing is possible. Partial flap loss might take a long time to heal. This may require frequent dressing changes or further surgery to remove the non-healed tissue. Smokers have a greater risk of skin loss and wound healing complications.

Major complications:

Urethral Fistula- urethral fistulas occur in around 7-15% of all metoidioplasty individuals and are repaired by excision of the fistula and overlaying with available local vascularised flaps.

Urethral stricture- urethral strictures occur in 2-3% of all individuals. Stricture plasty or buccal mucosal graft urethroplasty might be necessary to repair the stricture.

Testicular implant dislocation- in the event of a dislocated testicular implant, repositioning and fixation of the implant into proper position, along with creation of a new capsule are indicated.

Other complications:

Unsatisfactory result- You may be disappointed with the result of the surgery. It may be necessary to perform additional surgery to improve your results.

Allergic reactions- In rare cases, local allergies to tape, suture material, or topical preparations have been reported. Systemic reactions which are more serious may occur to drugs used during surgery and prescription medicines. Allergic reactions may require additional treatment.

Surgical anaesthesia- Both local and general anaesthesia involve risk. There is the possibility of complications, injury, and even death from all forms of surgical anaesthesia or sedation.

Additional surgery necessary- There are many variable conditions that may influence the long-term result of female to male gender reassignment surgery. Should complications occur, additional surgery or other treatments may be necessary. Even though risks and complications occur infrequently, the risks cited are particularly associated with gender reassignment surgery. Other complications and risks can occur but are even more uncommon. The practice of medicine and surgery is not an exact science. Although good results are expected, there is no guarantee or warranty expressed or implied, on the results that may be obtained.

Financial responsibilities

The cost of surgery involves several charges for the services provided. The total includes fees charged by your doctor, the cost of surgical supplies, laboratory tests, blood bank, anaesthesia, and hospital charges, depending on where the surgery is performed. Depending on whether the cost of surgery is covered by an insurance plan, you will be responsible for necessary co-payments, deductibles, and charges not covered.

Additional costs may occur should complications develop from the surgery. Secondary surgery or hospital day-surgery charges involved with reversionary surgery would also be your responsibility.

PART 2- CONSENT FORM

DISCLAIMER

Informed-consent documents are used to communicate information about the proposed surgical treatment of a disease or condition along with disclosure of risks and alternative forms of treatment(s). The informed-consent process attempts to define principles of risk disclosure that should generally meet the needs of most individuals in most circumstances.

However, informed consent documents should not be considered all-inclusive in defining other methods of care and risks encountered. Your plastic surgeon may provide you with additional or different information which is based on all the facts in your particular case and the state of medical knowledge.

Informed-consent documents are not intended to define or serve as the standard of medical care. Standards of medical care are determined on the basis of all of the facts involved in an individual case and are subject to change as scientific knowledge and technology advance and as practice patterns evolve.

CONSENT FOR SURGERY / PROCEDURE or TREATMENT

a) I hereby authorize Dr _____ and such assistants as may be selected to perform the following procedure or treatment**: Metaidoioplasty**
b) I consent to the presence of OR staff of either sex to be present in OR during my surgery. I understand that they are present for the safe conduct of my surgery.
c) I recognize that during the course of the operation and medical treatment or anaesthesia, unforeseen conditions may necessitate different procedures than those above. I therefore authorize the above physician and assistants or designees to perform such other procedures that are in the exercise of his or her professional judgment necessary and desirable. The authority granted under this paragraph shall include all conditions that require treatment and are not known to my physician at the time the procedure is begun.
d) I consent to the administration of such anaesthetics considered necessary or advisable. I understand that all forms of anaesthesia involve risk and the possibility of complications, injury, and sometimes death.
e) I understand what my surgeon can and cannot do, and I understand there are no warranties or guarantees, implied or specific about my outcome. I have had the opportunity to explain my goals and understand which desired outcomes are realistic and which are not. All my questions have been answered, and I understand the inherent (specific) risks of the procedures I seek, as well as those additional risks and complications, benefits, and alternatives. Understanding all of this, I elect to proceed.
f) I consent to be photographed or televised before, during, and after the operation(s) or procedure(s) to be performed, including appropriate portions of my body, for medical, scientific or educational purposes, provided my identity is not revealed by the pictures.
g) For purposes of advancing medical education, I consent to the admittance of observers to the operating room.

h) I consent to the utilization of blood products should they be deemed necessary by my surgeon and/or his/her appointees, and I am aware that there are potential significant risks to my health with their utilization.
i) I understand that the surgeon's fees are separate from the anaesthesia and hospital charges, and the fees are agreeable to me. If a secondary procedure is necessary, further expenditure will be required.
j) I realize that not having the operation is an option.
k) It has been explained to me in a way that i understand**:**
    a. The above treatment or procedure to be undertaken
    b. There may be alternative procedures or methods of treatment
    c. There are risks to the procedure or treatment proposed

I consent to the treatment or procedure. I am satisfied with the explanation.

Name of Individual…… Name of the Witness……

Relationship……

Signature……

Signature…….. Date……
Date……

Doctor……
Designation……Signature……
Date……

10) INDIVIDUAL INFORMATION AND INFORMED CONSENT FOR VOICE MODIFICATION

This is an informed-consent document that has been prepared to help inform you about voice modification surgery, its risks, and alternative treatments. This document consists of two parts- the first part is detailed information regarding the procedure and the next is procedure specific consent. Please go through the entire document before consenting to the procedure.

Part 1- Individual information

Introduction

Voice is a very important part of our identity, also of our gender identity and expression, because within seconds, most of us decide the gender of the person speaking. Individuals wishing to affirm the gender identity of their voice may benefit from surgical alteration of their sound- producing mechanism.

1) Indications

a. Individuals who cannot alter their voice through therapy or practice who want to be perceived as female by sound alone, such as during a telephone conversation

b. Individuals who can voluntarily alter their voice to sound female but wish to remove even the potential for inadvertently sounding male.
c. Individuals whose speaking pitch and vocal range have dropped from the complication of vocal cord detachment after tracheal shave.

2) Contraindications

a. Individuals who cannot tolerate the chance that surgery will not accomplish a pitch and/or resonance change; all surgeries have the risk of incomplete alteration of the voice from male to female
b. Individuals who cannot tolerate a loss of maximal volume are not surgical candidates.

3) Preoperative Requirements:

a. A voice recording might be made of the following vocal capabilities:

- Comfortable speaking pitch reading a standard passage of several sentences
- Lowest pitch that can be produced
- Highest pitch that can be produced.
- Loud phonation, a robust yell, cough and a throat clearing
- Soft singing of several words at high and low pitches, such as "Happy Birthday to You"

b. Endoscopic examination with audio might be done for visualising the cords.
c. Stopping health supplements such as omega, fish oils, herbal products, garlic, green tea etc from 2 weeks prior to surgery.
d. Stop smoking from 4 weeks prior to surgery.
e. Limit/ stop alcohol intake 4 weeks prior to surgery. Hormone therapy should be adjusted as per advice of treating endocrinologist.
f. Stop blood thinners if feasible, from 5 days prior to surgery with permission from individual's cardiologist.

4) Pre-operative Investigations:

a) Complete blood counts, coagulation profile, Blood sugar fasting and PP, LFT, RFT, TSH, viral markers for hepatitis B, C and HIV, EKG, Chest x ray.
b) voice recordings and endoscopy might be done for medicolegal purposes. Other specific investigations if required for co-existing conditions.

5) Procedure specific information:

a) General individual identifiers, names of admitting surgeons, individual's and witness's signatures, permission for photo and videography etc are usually part of general hospital consent and also may be a part of this consent. Higher risk due to some co-existing condition and anaesthesia consents are separate.
b) Various surgical techniques are available including- cricothyroid approximation, LASER vocal cord thinning, vocal cord webbing, anterior commissure advancement, anterior partial laryngectomy and thyrohyoid elevation.

The most common procedures done are CTA (cricothyroid approximation) and vocal cord webbing and will be discussed here:

6) CTA surgery mimics the normal action of the cricothyroid muscle to lengthen the vocal cord. The vocal quality produced by this increase in tension of the vocal cord is called a falsetto. The surgery can be done under general anaesthesia or under local anaesthesia.

The skin incision is made in the neck near the cricothyroid space, with the individual supine and head extended.

The thyroid and cricoid cartilage are visualised, and these cartilages are approximated with a permanent suture.

The neck incision is closed

After the surgery, no voice rest is required, and the individual can take bath after 24 hours.

ii) Vocal cord webbing is a procedure which shortens the effective length of the vocal cords so that the pitch is elevated. It is done with micro laryngoscopy under general anaesthesia. There will be no external incisions. the raw edges of the anterior vocal cords are sutured together. Individuals should rest their voice for 2 weeks after surgery.

6) <u>Complications</u> –

Note: The listed risks and complications are not all inclusive.

a) **Fading of elevated pitch** over time- some individuals can experience an initial elevation in pitch that fade back to a baseline pitch over a few months (33%)
b) Some individuals develop an **unnatural, hyper elevated** pitch ranging from an extreme falsetto to a mild falsetto quality
c) **Bleeding**- It is possible, though unusual, to experience a bleeding episode during or after surgery. Should post-operative bleeding occur, it may require emergency treatment to drain accumulated blood or blood transfusion. You should reveal all the medications that you have been taking to the surgeon so that medicines that can cause bleeding can be stopped or its dose adjusted before the surgery.
d) **Infection**- Bacteria live on the skin. You will be given antibiotics through your I.V. at the time of surgery and will take oral antibiotics following surgery. Although infection is unusual after this type of surgery, it may appear in the immediate post-operative period or at any time following the surgery. Should an infection occur, treatment including antibiotics, or additional surgery may be necessary.
e) **Skin scarring**- All surgical incisions produce scarring. The quality of these scars is unpredictable. Abnormal scars may occur within the skin and deeper tissue. In some cases, scars may require surgical revision or other treatments. Every effort will be made to minimize scars.
f) **Unsatisfactory result**- You may be disappointed with the result of the surgery. It may be necessary to perform additional surgery to improve your results.
g) **Allergic reactions**- In rare cases, local allergies to tape, suture material, or topical preparations have been reported. Systemic reactions which are more serious may occur to drugs used during surgery and prescription medicines. Allergic reactions may require additional treatment.
h) **Surgical anaesthesia**- Both local and general anaesthesia involve risk. There is the possibility of complications, injury, and even death from all forms of surgical anaesthesia or sedation.

i) **Additional surgery necessary-** There are many variable conditions that may influence the long-term result of voice feminisation surgery. Should complications occur, additional surgery or other treatments may be necessary. The practice of medicine and surgery is not an exact science. Although good results are expected, there is no guarantee or warranty expressed or implied, on the results that may be obtained.

7) Postoperative Course:

voice rest and speech therapy depend on the type of surgery performed. For cricothyroid approximation, no voice rest is required. individuals can take bath after 24 hours. For vocal cord webbing, voice rest for 2 weeks is necessary. After surgery, you'll have follow-up visits with a speech-language pathologist to make the most of your surgery, protect your vocal health and learn to use your changed voice.

8) Financial responsibilities:

The cost of surgery involves several charges for the services provided. The total includes fees charged by your doctor, the cost of surgical supplies, laboratory tests, blood bank, anaesthesia, and hospital charges, depending on where the surgery is performed. Depending on whether the cost of surgery is covered by an insurance plan, you will be responsible for necessary co-payments, deductibles, and charges not covered. Additional costs may occur should complications develop from the surgery. Secondary surgery or hospital day-surgery charges involved with reversionary surgery would also be your responsibility.

PART 2- CONSENT FORM

DISCLAIMER

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However, informed consent documents should not be considered all-inclusive in defining other methods of care and risks encountered. Your surgeon may provide you with additional or different information which is based on all the facts in your particular case and the state of medical knowledge.

Informed-consent documents are not intended to define or serve as the standard of medical care. Standards of medical care are determined on the basis of all of the facts involved in an individual case and are subject to change as scientific knowledge and technology advance and as practice patterns evolve.

CONSENT FOR SURGERY / PROCEDURE or TREATMENT

a) I hereby authorize Dr _____ and such assistants as may be selected to perform the following procedure or treatment**: gender affirming voice surgery.**

b) I consent to the presence of OR staff of either sex to be present in OR during my surgery. I understand that they are present for the safe conduct of my surgery.
c) I recognize that during the course of the operation and medical treatment or anesthesia, unforeseen conditions may necessitate different procedures than those above. I therefore authorize the above physician and assistants or designees to perform such other procedures that are in the exercise of his or her professional judgment necessary and desirable. The authority granted under this paragraph shall include all conditions that require treatment and are not known to my physician at the time the procedure is begun.
d) I consent to the administration of such anesthetics considered necessary or advisable. I understand that all forms of anesthesia involve risk and the possibility of complications, injury, and sometimes death.
e) I understand what my surgeon can and cannot do, and I understand there are no warranties or guarantees, implied or specific about my outcome. I have had the opportunity to explain my goals and understand which desired outcomes are realistic and which are not. All of my questions have been answered, and I understand the inherent (specific) risks of the procedures I seek, as well as those additional risks and complications, benefits, and alternatives. Understanding all of this, I elect to proceed.
f) I consent to be photographed, voice recorded or televised before, during, and after the operation(s) or procedure(s) to be performed, including appropriate portions of my body, for medical, scientific or educational purposes, provided my identity is not revealed by the pictures.
g) For purposes of advancing medical education, I consent to the admittance of observers to the operating room.
h) I consent to the utilization of blood products should they be deemed necessary by my surgeon and/or his/her appointees, and I am aware that there are potential significant risks to my health with their utilization.
i) I understand that the surgeon's fees are separate from the anaesthesia and hospital charges, and the fees are agreeable to me. If a secondary procedure is necessary, further expenditure will be required.
j) I realize that not having the operation is an option.
k) It has been explained to me in a way that i understand**:**
    a. The above treatment or procedure to be undertaken
    b. There may be alternative procedures or methods of treatment
    c. There are risks to the procedure or treatment proposed

I consent to the treatment or procedure. I am satisfied with the explanation.

Name of Individual……Signature of Pt……..……

Date……

Name of the Witness……

Relationship……

Signature of witness……

Date……

Name of doctor……

Designation……

Signature……

Date……

11) CONSENT FOR VOICE RECORDING / MEDICAL PHOTOGRAPHY/ VIDEOGRAPHY

I,_____ aged _____ years, Hospital ID_____, hereby grant Dr _____ or designee permission to take voice recordings and /or video of myself.

I understand that photographs/ voice recordings/ video may be taken before, during and after my procedure(s) as a routine part of my medical care. I am aware that the photographs may be used for any lawful purpose including, but not limited to the hospital/doctor's website, social media accounts, promotional materials, either digital or in print, in perpetuity.

I authorize the use of my photographs and voice recordings for doctor's photo gallery to help future individuals understand and see outcomes from surgery/treatment. I understand that the information may be used in my medical records, for purposes of medical teaching, or for publication in medical journals.

By consenting to these voice recordings and photography, I understand that I will not receive payment from any party. Refusal to consent to photographs will in no way affect the medical care I receive. I release and discharge above mentioned doctor and the hospital from all rights that I may have in the photographs/voice recordings/ video and from any claim that I may have relating to such use in publication, including any claim for payment in connection for distribution or publication of the photographs.

I understand that I will not be identified by name in any use of these photographs/videos (unless I state my name). I understand that in some circumstances the photographs may

portray features which make my identity recognizable. Jewelry, tattoos, distinctive clothing / other features may also reveal my identity.

By signing this consent, I authorize doctor and the hospital to edit, alter, share, remix, tweak, build upon or in any way alter the photographs/voice recordings/ video mentioned above.

I am more than 18 years of age. I understand the scientific facts that have been discussed with me as well as the contents of this consent form. I have been given the opportunity to discuss regarding the treatment plan. I also had the opportunity to ask questions and have received satisfactory answers in a language I understand.

I have signed this consent voluntarily it of my free will without any compulsion and in my full senses.

Name of Individual……Signature of Pt……

Date……

Name of the Doctor……Designation…….

Signature…… Date……

Public Health Approach to Gender Incongruence

Contributing Authors

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Introduction

Gender incongruence is defined as the mismatch an individual feel as a result of the discrepancy experienced between their gender identity and the gender assigned at birth. The discomfort associated with this incongruence is described as gender dysphoria (Gires, 2019).

The term 'Gender Incongruence' has been introduced as a condition under 'Conditions related to Sexual Health' in the latest International Statistical Classification of Diseases and Related Health Problems (ICD-11), released by the World Health Organization on 18th June 2018 (M. Fernández Rodríguez, 2018). These changes of ICD-11 represent a breakthrough and a great sense of freedom for transgender people. This step, which undoubtedly reflects the progressive mindset of the Medical Fraternity, will go down in the annals of the history of Modern Medicine as the turning point. Henceforth the existence of the Gender Spectrum has been validated and a platform prepared for addressing the issues arising out of nonconformity to the populist binary view of gender held by the society at large without the attached stigma of Mental Illness. Though the debate on the appropriateness of the label of Gender Incongruence continues to rage among the academicians and several other wrinkles also need to be ironed out, it is nevertheless a positive step towards delivery of healthcare to this marginalized and oft-neglected subset of society. Another significant step is the complete removal of Homosexuality from the ICD-11, which validates the current scientific stand that 'Sexual orientation' is a matter of personal choice and not a medical issue.

'Gender' is the pedestal on which the construct of 'I' or 'Self' stands. It is the foundation of 'Identity', what one sees oneself as and what one desires to project to the environment irrespective of the genotype inherited or phenotype exhibited. Gender is by and large a social construct and has cultural relevance. Gender Identity and Sexual orientation are recognized as separate entities and are not binary. Gender is a multifaceted spectrum manifested by the self-assigned role and expression which cannot be limited to Male or Female.

There have been a few studies to enumerate transgender population; however, no such enumeration is available for Gender Incongruence. Transgender is an umbrella term used to describe a wide range of identities whose appearance and characteristics are perceived as gender-atypical —including transsexual people, cross-dressers (sometimes referred to as "transvestites"), and people who identify as the third gender (UNFE, Definitions, n.d.). A study published in The Lancet in June 2016 estimates 25 million people, or 0.3 to 0.5% of the global population, as Transgender (Balakrishnan, 2016). Perhaps this is the only accurate estimation available for the worldwide population of Transgender. In the same article, the author cites significant health inequities leading to inaccessible health services because of their social and economic marginalisation. The findings on the health aspect were published by Reisner and his colleagues in The Lancet. A GAP report from UNAIDS cites that estimates from countries indicate that the transgender population could be between 0.1% and 1.1% of reproductive age adults (UNAIDS, 2014). As per Census 2011 in India, there are approx. 4.9 Lakhs people in the Others category (which includes Transgender) in the country.

There are very few estimates available for gender incongruence. Two recent population studies have aimed to estimate the prevalence of people who identify as such. Kuyper & Wijsen (2014) examined self-reported gender identity and dysphoria in a large Dutch population sample, and found that 1.1% of people assigned male at birth and 0.8% of people assigned female at birth reported an 'incongruent gender identity', defined as stronger

identification with other sex as with sex assigned at birth (Lisette Kuyper, 2014). Similarly, Van Caenegem et al. (2015) reported results based on two population-based surveys in Belgium. In the general population, gender incongruence was found in 0.7% of men and 0.6% of women. In sexual minority individuals, the same was 0.9% in men and 2.1% in women (Van Caenegem E, 2015).

Census, an exercise to count the population in India, never recognised Hijra/ Transgender until 2011. In 2011, for the first time, it collected data of Transgender with details related to their employment, literacy, and caste. As per this, out of the total estimated population of 1.247 billion, people who have identified themselves as transgender persons, constitute 4,87,303 (Mandal, n.d.). Though Census 2011, mentions above number in the "Others" category (GoI, 2019), various other literature hints towards a higher figure of about 5-6 million eunuchs in India (Mal, 2018).

Even if the census gives a figure of the transgender population, we do not know how many people with gender incongruence are there, or how many of them experience a need for health care, which poses a big problem for healthcare planners. The first challenging task for the survey researcher in this area will be to decide whom to count and by what means in the upcoming census.

Gender identification is the steppingstone for psychosocial development. Gender recognition, though starting very early in childhood, may remain fluid through a large portion of the growing years before gender affirmation finally crystallizes. This fluidity, in some cases, may extend right through adolescence into adulthood. A conflict arising as a result of incongruity between assigned sex and desired gender leads to dysphoria and non-resolution may distort psychosocial development, thereby manifesting as deviant behaviour, delinquency, mental ill-health, high-risk behaviour and conditions related to sexual health. This is further compounded by the insensitive callous attitude of the cisgender majority looking at them through the narrow prism of their own preconceived notions, perpetuating an environment of mistrust and intolerance and threat of ostracization, thus forcing the gender incongruent child/adolescent to solicit advice through the unmonitored electronic media exposing themselves to further harm at the hands of unscrupulous professionals who peddle street hormones and offer unscientific 'quick fix' procedures.

It has been documented that early recognition of gender incongruence, provisioning of a gender-sensitive environment for psychosocial development and early access to Healthcare services when coupled with social support, especially acceptance by parents, markedly reduces dysphoria, incidence of mental illness, risk-taking behaviour and sexual health issues. Hence it is of paramount importance that a multipronged proactive approach is adopted for the management of gender incongruence. The stakeholders need to acquire and share knowledge, facilitate the delivery of multispecialty healthcare, empower through advocacy and implement strong legislation for getting these outliers of society into the mainstream as productive citizens.

Discussion:

A holistic public health approach needs to be adopted by all agencies working to ensure equity in the delivery of healthcare. Existing policies, designed to address the problem, need to be reworked to address the cause rather than manage the outcomes. The task is compounded by not only the binary viewpoint and inadequate understanding of the "Transgender

Experience" by the agencies, both Governmental and Non-Governmental, entrusted with the task of giving succor, but also the inherent mistrust by the community of the cis population. To make matters worse, the majority of the transgender persons have poor health-seeking behaviour. The misinformed impressionable "client" is drawn to "Procedures" being offered in an unethical, covert manner to a privileged few who can afford the high costs. The non-existence of Indian Standards of Care and non-adherence to existing protocols lead to further harm. The absence of recognized Centers of Excellence adhering to the norms laid down by national and/or international professional bodies in the country capable of providing Training, Certification and Continuing Medical Education to the professionals desirous of / working in the field of Transgender Medicine and Surgery, adds fuel to the fire by promoting the growth of self-styled experts, who assume the role of gatekeepers, ready to cut corners and flaunt rules for financial gains. Their demand for unnecessary affidavits designed to absolve them of any legal action for procedures carried out over and above the minimum documentation needed for the protection of the interests of the transgender person, further adds to the dysphoria and make the journey of transitioning more arduous. Non-availability of trained manpower working in the Government Sector and absence of the much-needed Government aid / Political will and infrastructure puts affordable healthcare out of reach of this misunderstood, marginalized and often ostracized subset of society. Thus, denying them the fundamental human rights and opportunities to live with dignity as bestowed upon each citizen by the Constitution of India and reinforced by the various international fora of which India is a signatory.

Concerted efforts are needed to bring together, the professionals already working in the field of Transgender Health, educationists, academicians and social workers, on a common platform, wherein, they can step out of their silos, interact with each other and share their experiences to undertake formulation of Indian Standards of Care and work towards provisioning of a holistic and affordable Healthcare to all human forms, irrespective of their self-affirmed gender identity or sexual orientation. Dissemination of knowledge regarding Gender to the Primary Care Providers is essential for early recognition and prevention of gender dysphoria. Development of a progressive society mandates provisioning of a robust, customized healthcare infrastructure which addresses the unique needs and a nurturing, inclusive, social environment which seeks to harness the full potential of this often neglected vibrant human resource by encouraging empowerment and mainstreaming.

Recommendation:

It is important to nurture and promote collaboration between academic institutions, implementing structures and international bodies working on or with the Transgender communities to not only fill the lacunae in Primary, Secondary and Tertiary Healthcare but also to lay down the benchmarks in the delivery of standardized healthcare to the Transgender community in India.

The following action plan, based on a Public Health approach resting on the four domains of Knowledge, Healthcare, Empowerment and Mainstreaming, is proposed.

The domain of Knowledge:

1. **Setting up of a "Centre of Excellence in Transgender Health" at an academic institution**
   As the first step in the multipronged approach, it is recommended to set up a "Centre of Excellence in Transgender Health" at one of the top Universities of India having on its

campus all the requisite departments needed for imparting education in the Medical, Nursing, Paramedical, Social, and Legal fields, but also houses a Pharmacy and a Hospital.

The Centre shall function as the seat of academic excellence imparting training and education to the professionals from the Medical, Nursing, Paramedical, Legal and Social streams in the best practices in Transgender Health in collaboration with WPATH (World Professional Association for Transgender Health). It shall promote evidence-based care, education, research, advocacy and public policy in Transgender Health and set the benchmark for the delivery of Transgender Healthcare in the country. Taking a cue from the current Standards of Care developed by WPATH, the Centre shall, in light of the Indian cultural context, set the Indian Standards of Care. It shall formulate a curriculum specific to the Indian cultural context to enable proficiency in the implementation of the current Indian Standards of Care for delivery of healthcare to the Transgender and Gender nonconforming persons.

The Centre shall run Short term courses starting with a foundation course followed by Advance Courses leading to a Certification course in Transgender Medicine and Surgery.

The short term training courses shall include a Foundation Course in interdisciplinary Transgender Healthcare, Advanced Courses in Mental Health, Advanced Course in Non-Surgical Gender Affirmation Therapies, Advanced Course in Surgical Gender Affirmation Therapies, Advanced Child and Adolescent Transgender Healthcare Course, Course in Transgender Health Planning and Documentation and a Course in Law and Ethics in Transgender Health.

The Centre shall also conduct Continuing Medical Education Workshops containing highly specialized 4-8-hour interactive and/or case-based sessions focused on specific areas of interest for professionals who have completed the Foundations in Transgender Health course. Topics would include - Working with Children and Adolescents; Planning and Documenting for Medical Transition; Ethical Considerations; Pre and Post-Operative Surgical Care; Voice and Communication.

The Centre of Excellence shall also run an outreach programme for sensitization of the primary caregivers, schoolteachers, parents and employers regarding gender-related issues and help them develop gender-friendly safe spaces

The long-term goal is to create a faculty of international standing who shall mentor professionals to excel in the field of Transgender Health and pioneer research aligned to meet the needs of the community.

2. Conduct intensive IEC activities

Intensive IEC activities need to be conducted for raising awareness and among all stakeholders for mitigating the risk of communicable and non-communicable diseases as a result of the high vulnerability of the community members. For running innovative IEC campaigns, the involvement of national and international agencies with prior knowledge and expertise will be required.

The domain of Healthcare:

3. **Setting up of a Gender Clinic at the Hospital**
   Provisioning of affordable and accessible primary, secondary and tertiary care to the community members will be made possible by setting up a Gender Clinic at the Hospital. The gender clinic shall not only provide a hands-on training ground to the students but also allow them to closely interact with and develop a deeper understanding of the community.

4. **Develop a Department of Transgender Medicine and Surgery at Medical College**
   Introduction of Transgender Medicine and Surgery as a separate subject in the Medical curriculum is needed to ensure that every Medical student is aware of the special needs of the Transgender and Gender Nonconforming Persons and issues such as sexual and reproductive health, care of the aging transgender person and preventive healthcare can be addressed by professionals having sound knowledge and proper training. Role of National Medical Council and the Ministry of Health and Family Welfare is supreme for achieving this goal.

The domain of Empowerment:

5. **Setting up of a Gender Ethics Committee and Legal Cell**
   It is of paramount importance to set up an ethics committee and legal cell at the University, to prevent gatekeeping and unethical practices. This cell will work closely with the Gender Team to protect the interests of the Transgender persons and also that of the professionals providing care.

6. **Providing Health Insurance cover and Government Support for Gender affirming therapies**
   Gender Affirming therapies for affecting transition, though considered essential for reducing/preventing dysphoria, are not covered by Medical Insurance/government health schemes. The exorbitant price of treatment in private institutes makes it inaccessible for the large majority. A dialogue with the Insurance sector to address this issue and engagement with the Government to include gender-affirming therapies under the purview of the Government Health Schemes such as Ayushman Bharat will be required to move ahead.

7. **Provisioning of a Single Window for change of Gender in official documents**
   Change of name and gender in official documents such as Aadhar Card, PAN Card, Driving License, Voter ID card, Passport, educational qualifications etc. is an integral part of social transitioning. The Transgender person is often harassed and their dysphoria increases, as he is forced to come face to face with insensitive and prejudiced officials. It is proposed that a single window be set up by the Government for change of name and gender in all official documents.

Domain of Mainstreaming:

8. **Reservation and Social protection as regards Education, Housing and avenues for earning a livelihood.**
   It is recommended that all State Governments should act in accordance to the directions of the Honorable Supreme Court by engaging with the community and form the

Transgender Welfare Boards to address the felt needs as regards Education, Housing and avenues for earning a livelihood.

Conclusion

The vision of an all-inclusive society, wherein, all forms of gender identity and expression are nurtured and celebrated, where, new abilities emerging as a result of scientific progress permit all form of the human to live in harmony with dignity, embracing diversity and enjoying equal rights and privileges, as bestowed by the constitution, can indeed be converted into reality by making a concerted and coordinated effort, harnessing the time tested strengths and expertise of the various national and international agencies working with or assisting the Government in providing Social Justice and Health for All.

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Parents Support Group

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How Parent Support Groups Can Help Improve Healthcare for Transgender Youngsters

As a parent, one often wonders as to whether one is doing parenting right. At the best of times parenting is a challenging job. It's a non-stop, relentless 24/7 job. Most of us struggle even when times are good, and the going is all along a beaten path. When it comes to supporting transgender children, the job gets infinitely more complex. There is no help, no guidance because no one around us knows anything. With little to no societal guidance or help, parents of transgender children are often helpless and are on the lookout for help, support and guidance. Internet may help but it is not reliable. In matters pertaining to trans issues, the internet may actually even be a bit problematic. The authenticity of information available and also the quality of it can very well be suspect. Most of it comes from western sources and is therefore not quite what works in our sociocultural milieu. Even the medical info available is mostly of western origin and therefore can be a bit off context for our country. How can we develop a support system for parents of transgender children? Where do the parents of trans kids go, when they need moral support and guidance?

Our country has lacked support groups for almost everything. Unlike the west, support groups have not existed in our country, in general. But things are beginning to change. Support groups have recently come up to help parents find support from other parents who have similar lived experiences. I am myself, a member of Sweekar. The Rainbow Parents group. It's a group of parents of Indian origin from across the globe. All of us in this group are parents of LGBTQIA+ children. The group provides a safe space for parents where they can find support from other parents having similar lived experiences. The group has been a source of much needed moral support and often beyond. Here, I have met many parents of LGBTQIA+ children. We all share the same concerns and challenges and have all been the source of great help for each other. Moral support that we offer to each other is priceless. And, it's not just that. The very fact that we see other parents proudly standing up for their children gives us hope courage and strength. So far however, our role has been to support each other and to provide advocacy for the cause of LGBTQIA+ communities. Through this write up, I plan to suggest a more comprehensive role for such groups (PSGs from now), especially in the context of transgender children and their specific needs. Let me highlight some areas where parents support groups (PSGs) can be of great help.

The bridge between medical care givers and families of transgender children

Transgender children and their families have this difficult challenge of finding the right medical care givers. Trans kids require many different medical interventions. They need psychiatric treatments and counselling to mitigate their dysphoria and distress related with social issues they face. They need endocrinologists to supervise their feminizing/masculinizing hormone therapies. Also, many if not all need surgeries to alter their primary and secondary sex characteristics. In addition, they might require medical interventions to help them with other medical conditions. PSGs can help children to develop an understanding of the medical procedures and their realistically expected outcomes. Also, the help that such PSGs can provide in identifying competent and gender friendly medical professionals would be simply

priceless. Such medical care providers are rare and therefore hard to find. PSGs can therefore be that much needed bridge between medical professionals and trans youngsters.

Help parents of transgender children understand their medical needs

Transgender children have a lot of needs that are specific to them. These require parental support. For instance, they need to be their 'authentic self.' They have to explore their true identity to get to know themselves. It may be very difficult for parents of a child they have brought up say, as a boy, to explore their feminine side. It is however of existential importance to the child. Parents often need to be counselled and should seek help from professional counsellors. They need to be convinced to reach out to counsellors for their own mental health and that of the child. The PSGs can easily provide this guidance and convince parents to take the right steps in this direction. Here a PSG can be the ideal bridge between mental healthcare professionals/counsellors and families of trans children.

Watchdogs

PSGs also have an important role in guiding parents in avoiding medical procedures that are detrimental for children. A lot has been discussed in this regard in the IPATHCON conferences. This is of special importance in case of surgeries that are performed on intersex children before they attain the age of consent. Any lifelong body alterations must wait till the child has attained maturity and is capable of understanding their gender identity and expression. Such surgeries have been performed routinely in the past and the practice must stop. PSGs can easily be the watchdogs and help the parents of intersex children avoid such catastrophes. There is also the need to stop other malpractices like DIY hormone therapy tried out by children. Such instances are very common in countries like the UK, where there is a three to four year waiting list for appointments at NHS gender clinics. In such instance's parents must guide children and their families to find professional help where it's is available before taking up any treatment. Any and every treatment must be under medical supervision, by appropriate medical professionals. PSGs can easily act as watchdogs in this regard and safeguard the children.

Here, I would also like to make two important points regarding practices by young trans children. One is the practice of using breast binders by young transmen to 'pass' as men. This is fine if done occasionally. However, if it's done on a regular basis for prolonged periods of time, it starts to alter the nature of tissues creating problems for appropriate surgeries later. The exact same caveats can be made for the practice of 'tucking' the genitals by young transitioning transwomen. This too causes similar problems for surgeons performing gender affirming surgeries later. Parents must make themselves aware of these issues and help their children avoid these practices.

Ensuring a conducive environment for diverse children in schools and educational institutions

There is a huge need for parents to find representation in the PTAs of schools to guide school managements to have policies in place so that children who belong to the LGBTQIA+

spectrum have their needs taken care of. Such children are often bullied and therefore end up deprived of the education they deserve.

For instance, transgender and intersex children have a need for gender neutral bathrooms in schools. Schools need to be made aware of this need. PSGs can do the job here. They can help schools in ensuring inclusive policies and practices for LGBTQIA+ children.

Bring in policy changes at the government level for ensuring equity

According to some recent research, as much as 15% of the population belongs to the LGBTQIA+ spectrum. Hence, they are not the miniscule minority as was the belief earlier. There is a need for activism to ensure political representation for such communities. Here, PSGs can be the activists to ensure policy changes at the level of government to make our country truly inclusive. PSGs can be the harbingers of change at the highest levels of government.

Be the change

The last but not the least. Parents can be the change agents in the society by being the change themselves. By proudly supporting their children and being the example for the society, parents of transgender children can be the agents of change.

When we saw other parents in our parents support group, we felt that we are not alone. To see other parents like ourselves, supporting their children, was a great source of strength and courage for us. Here lies the single most important role that the PSGs can play. To all parents who are struggling with the challenges faced by them we offer a hand of help. As parents and PSGs we promise to be the paradigm for the world at large. We appreciate the work being done by **ATHI** in association with **Jamia Hamdard.** These are stellar organizations and the work being done by them must be recognized. Let us all stand together and be the agents of positive change.

When it comes to being the change agents, parents of transitioning trans children do need advice from those with experience. Therefore, to give parents a helping hand, we have compiled an ABC of parenting checklist. I would suggest parents of transitioning young children to go through this and benefit from it. So here it goes.

The Alphabet of parenting a Transgender child

Accept

Be an ally, not an adversary

Confidence of the child is very fragile, maintain it.

Do not be afraid, and do not be in a denial

Embrace the child wholeheartedly

Follow the lead given by the child

Get rid of guilt, and get information, arm yourself.

Happiness of the child is paramount, get Help if needed.

Ignore all kinds of negativity, whether from relatives or friends.

Judging a person on the basis of their preferences or gender is never right. Your child deserves this consideration.

Knowledge is power, educate yourself

Laws are there to protect you and your family. Know the legality.

Mental health professionals are needed only to dispel dysphoria, seek medical help when required.

Not an illness, No treatment can "cure" gender incongruence.

Be Open in communication, not opinionated.

Professional help for hormonal/surgical treatment should be sought when necessary

Question/ queries often help getting you on the right path. Ask continuously.

Raise happy children

Support groups are helpful. Get in touch with similar minded people.

It's a Teamwork where the leader is the child.

Understand the child's viewpoint

Variation is part of nature, accept it.

"Why me?" is to be replaced with "Yay me".

Xpress yourself positively.

You are the chosen one to bring about a change.

Embrace your calling with a Zeal.

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